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(71) Applicant *(for all designated States except US)*: **NOVO NORDISK A/S** [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **KLITGAARD, Peter, Christian** [DK/DK]; Astershaven 49, DK-2765 Smørum (DK).

(74) Common Representative: **NOVO NORDISK A/S**; Corporate Patents, Novo Allé, DK-2880 Bagsværd (DK).

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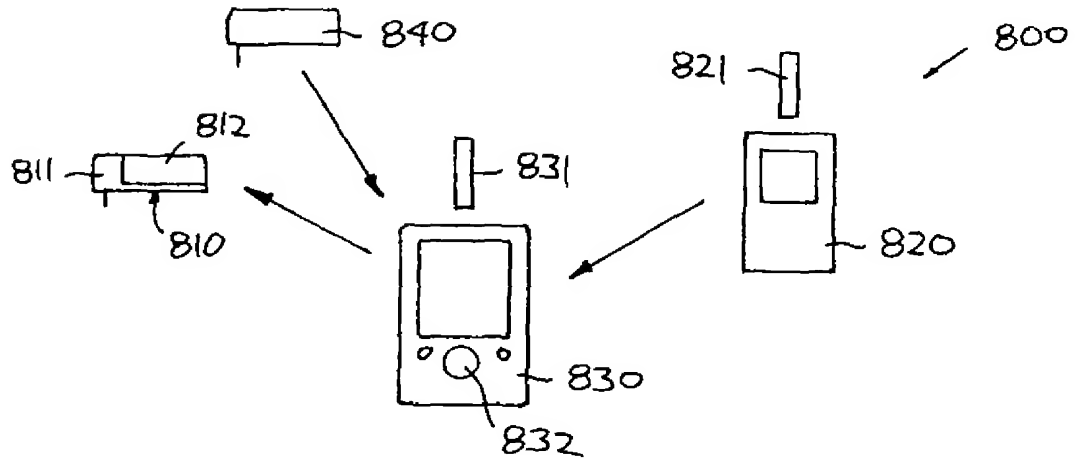

(57) Abstract: A medical system is provided comprising a sensor unit and a receiving unit is provided, the sensor unit being adapted to generate sensor data indicative of a time-dependent characteristic of a subject, and transmit data to a receiver at intervals determined by an analysis of time-dependent changes in the generated sensor data, the receiving unit being adapted to receive sensor data at a non-predetermined rate. By this arrangement sensor data can be transmitted only when considered necessary in accordance with a predetermined strategy, this reducing the energy consumption associated with the transmission of data. The strategy may set out that the transmission of sensor data is skipped in case there is no or only a small change in an actual sensor data value. On the other hand, in case of rapid changes in sensor data values, sensor data may be transmitted at higher rate.

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MEDICAL SYSTEM COMPRISING A SENSOR DEVICE

The present invention generally relates to communication between a sensor device and a further device. In specific aspects the sensor device provides continuous or quasi-continuous data representative of a body characteristic of a subject, the sensor data being transmitted to the further device in an efficient way.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by injection or infusion of insulin, however, this is only an exemplary use of the present invention.

Portable drug delivery devices for delivering a drug to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug and having an outlet in fluid communication with a hollow infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. Such devices are often termed infusion pumps.

Basically, infusion pumps can be divided into two classes. The first class comprises infusion pumps which are relatively expensive pumps intended for 3-4 years use, for which reason the initial cost for such a pump often is a barrier to this type of therapy. Although more complex than traditional syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

Addressing the above problem, several attempts have been made to provide a second class of drug infusion devices that are low in cost and convenient to use. Some of these devices are intended to be partially or entirely disposable and may provide many of the advantages associated with an infusion pump without the attendant cost and inconveniencies, e.g. the pump may be prefilled thus avoiding the need for filling or refilling a drug reservoir. Examples of this type of infusion devices are known from US patents 4,340,048 and 4,552,561 (based on osmotic pumps), US patent 5,858,001 (based on a piston pump), US patent 6,280,148 (based on a membrane pump), US patent 5,957,895 (based on a flow restrictor pump (also know as a bleeding hole pump)), US patent 5,527,288 (based on a gas generating pump), or US patent 5,814,020 (based on a swellable gel) which all in the last decades have been pro-

posed for use in inexpensive, primarily disposable drug infusion devices, the cited documents being incorporated by reference. US patent 6,364,865 discloses a manually held infusion device allowing two vial-type containers to be connected and a pressure to be build up in one of the containers to thereby expel a drug contained in that container.

The disposable pumps generally comprises a skin-contacting mounting surface adapted for application to the skin of a subject by adhesive means, and with the infusion needle arranged such that in a situation of use it projects from the mounting surface to thereby penetrate the skin of the subject, whereby the place where the needle penetrates the skin is covered while the appliance is in use. The infusion needle may be arranged to permanently project from the mounting surface such that the needle is inserted simultaneously with the application of the infusion pump, this as disclosed in US patents 2,605,765, 4,340,048 and in EP 1 177 802, or the needle may be supplied with the device in a retracted state, i.e. with the distal pointed end of the needle "hidden" inside the pump device, this allowing the user to place the pump device on the skin without the possibility of observing the needle, this as disclosed in US patents 5,858,001 and 5,814,020. In addition to pumps, alternative means for transporting a fluid drug may be used, e.g. iontophoresis as discussed below.

To reduce the costs of a disposable pump system, the system may comprise a pump unit per se in combination with a wireless remote controller, this allowing the pump unit to be provided with only a reduced user interface for in- and out-putting data to and from the pump, the user interface being arranged on the remote controller, see e.g. EP 1 177 802 and EP 1 332 440. As the pump unit may be carried or mounted under clothing, a remote controller may also improve operation of the system, for which reason it has also been proposed for a traditional durable type of pump, see e.g. US patent 6,641,533.

Although drug infusion pumps, either disposable or durable, may provide convenience of use and improved treatment control, it has long been an object to provide a drug infusion system for the treatment of e.g. diabetes which would rely on closed loop control, i.e. being more or less fully automatic, such a system being based on the measurement of a value indicative of the condition treated, e.g. the blood glucose level in case of insulin treatment of diabetes. Alternatively, the system may be an "open loop" system in which infusion parameters are automatically calculated on the basis of received data, however, instead of automatically implementing the calculated values, the user is asked to confirm the proposed changes. The user may also be allowed to manually change the proposed value based on personal experience.

A given monitor system for measuring the concentration of a given substance may be based on invasive or non-invasive measuring principles. An example of the latter would be a non-invasive glucose monitor arranged on the skin surface of a patient and using near-IR spectroscopy, however, the present invention is concerned primarily with devices comprising a transcutaneous device such as a needle-formed sensor element.

The sensor may be placed subcutaneously being connected to external equipment by wiring or the substance (e.g. fluid) to be analysed may be transported to an external sensor element, both arrangements requiring the placement of a subcutaneous component (e.g. small catheter or tubing), the present invention addressing both arrangements. However, for simplicity the term "sensor" is used in the following for both types of elements introduced into the subject.

A sensor system may be formed integrally with a given pump device, however, the recently proposed sensor systems are discrete systems (e.g. implantable, semi-implantable, or skin-mountable) relying on wireless communication between a sensor unit and a further unit, e.g. a remote controller as described above, an external pump unit or an implantable pump, see e.g. US patents 5,569,186, 6,558,320 and 6,641,533 which are hereby incorporated by reference. A sensor unit may also be used to merely record data for either immediate display to the user and/or for subsequent utilization by e.g. a physician, without the data being used in an open or closed loop system.

DISCLOSURE OF THE INVENTION

Having regard to the above-identified systems, it is an object of the present invention to provide a system comprising a sensor device and a further device in which communication between the two devices takes place in an efficient yet reliable way. In a specific aspect, it is an object to provide a wireless communication protocol which allows two devices to communicate in an energy efficient way.

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

Thus, corresponding to a first aspect, a medical system comprising a sensor unit and a receiving unit is provided, the sensor unit being adapted to generate sensor data indicative of a time-dependent characteristic of a subject, and transmit data to the receiving unit at intervals determined by an analysis of time-dependent changes in the generated sensor data, the receiving unit being adapted to receive sensor data at a non-predetermined rate. In the context of the present disclosure, the term unit is used to characterize both a sub-unit to be used in combination with one or more further components, as well as a self-contained "complete" unit.

By this arrangement sensor data can be transmitted only when considered necessary in accordance with a predetermined strategy, this reducing the energy consumption associated with the transmission of data, e.g. when data is transmitted wirelessly. The strategy may set out that the transmission of sensor data is skipped in case there is no or only a small change in an actual sensor data value. On the other hand, in case of rapid changes in sensor data values, sensor data may be transmitted at a higher rate.

The sensor unit comprises a sensor device *per se*, e.g. a transcutaneous sensor adapted to provide an analyte concentration-dependent signal, a processor adapted to process and evaluate signals received from the sensor device, and a transmitter associated with the processor for transmitting sensor data. The transmitted data may be in the form of "raw" sensor signals, e.g. a voltage generated by the sensor device, which is then subsequently utilized in the receiving unit, or the data may represent calculated values for the measured analyte, e.g. a blood glucose value. Correspondingly, the receiving unit comprises a processor and a receiver associated with the processor for receiving sensor data. Alternatively, the time-dependent characteristic of a subject may be based on electric occurrences, e.g. heart or brain activity (EKG or ECG).

In an exemplary embodiment the receiving unit comprises a display for graphically displaying sensor data related information (i.e. received values or values calculated on the basis of received data) as a function of time, e.g. as a continuous graphical representation. However, as sensor data in most cases and in accordance with the first aspect of the present invention is received at non-constant intervals, the receiving unit is adapted to generate estimated sensor data values for the time intervals at which no sensor data has been received from the sensor unit. Typically, the receiving unit will assume that no change has taken place and will accordingly display an unchanged value. This said, the sensor unit may be adapted to store

sensor data values in a memory and transmit the stored values to the receiving unit at a desired point of time. In this way the estimated values can be retroactively updated.

To save energy in both the transmitting and receiving device, the system may comprise a telemetry system in which sensor data are transmitted during synchronized, pre-selected transmission respectively receiving windows of time, i.e. the transmitter and receiver are not energized in the periods between the transmission/receiving windows. Synchronization is typically established during mating of the two units and is adjusted during operation in case any drifting is detected. A medical system using this principle is disclosed in US 5,748,103. By transmitting sensor data only when considered necessary in accordance with a predetermined strategy, energy consumption associated with the transmission of data can be lowered in the sensor device. However, it may also be relevant to lower energy consumption in the receiving device by reducing the number of open receiving windows.

Thus, according to an embodiment of the invention, the periods of time between receiving windows are controlled by the sensor unit and determined by an analysis of the time-dependent changes in the generated sensor data. More specifically, the sensor unit may be adapted to detect periods with only minor variations in the measured level of a given analyte, and correspondingly instruct the receiving unit to open the receiving windows at longer intervals, e.g. every 5 minutes instead of every 1 minute. To further reduce energy consumption in the units, the length of periods between transmitting and/or receiving windows may be programmable, this allowing e.g. a slower update during the night.

In a specific embodiment of the invention the receiving unit is in the form of a remote controller adapted to transmit instructions to a drug delivery device, e.g. by means of RF or IR communication. Alternatively, the receiving unit may be in the form of a drug delivery device *per se* comprising a reservoir and pump means.

The receiving unit may be adapted to use the received sensor data to calculate delivery parameters for use in the drug delivery device, e.g. to calculate a correction bolus or, in combination with other data, a meal bolus.

In a further aspect of the invention a medical sensor unit *per se* is provided, the unit being adapted to generate sensor data indicative of a time-dependent characteristic of a subject, and transmit data to a receiver at intervals determined by an analysis of time-dependent changes in the generated sensor data. Embodiments of the sensor unit may comprise addi-

tional features as described for a sensor unit above. In a yet further aspect, a receiving unit as described above is provided.

The present invention also provided a method of operating a medical system, comprising the steps of (a) providing a sensor unit and a receiving unit, the sensor unit being adapted to generate sensor data indicative of a time-dependent characteristic of a subject, and (b) transmitting data to the receiving unit at intervals determined by an analysis of time-dependent changes in the generated sensor data, wherein the receiving unit is adapted to receive sensor data at a non-predetermined rate.

In specific embodiments of the invention, a medical device comprising a transcutaneous unit and a process unit is provided, wherein the transcutaneous device unit comprises a transcutaneous device, and a mounting surface adapted for application to the skin of the subject, and wherein the process unit comprises a process assembly adapted to cooperate with the transcutaneous device, wherein the transcutaneous device unit and the process unit are adapted to be secured to each other to form a unitary device. As appears, such a transcutaneous unit may be adapted to serve either as a sensor unit or a receiving pump unit as described above.

Thus, the term “process assembly” covers an aggregation of components which are adapted to interact with the transcutaneous device to provide a given functionality. For example, the transcutaneous device may be in the form of a transcutaneous sensor device, and the process assembly comprises a processor adapted to transmit and/or process data acquired via the sensor device.

In another example, the transcutaneous device is in the form of a transcutaneous access device, and the process assembly comprises a reservoir adapted to contain a fluid drug, an expelling assembly adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the skin of the subject via the transcutaneous access device, and a processor for controlling the expelling assembly. Such a medical device may be used in a system further comprising a remote control unit comprising a processor, the medical device and the remote control unit being adapted to transmit data therebetween. The remote control unit may be adapted to receive externally supplied values and calculate a bolus amount of drug to be infused based upon the externally supplied values, e.g. it may be adapted to calculate a bolus amount of drug to be infused based upon externally supplied values representing material to be ingested by the body of the subject. The system may comprise a first analyte

sensor device adapted to provide data indicative of a concentration of the first analyte in the user, the remote control unit comprising an infusion calculator for calculating a bolus or infusion rate on the basis of data supplied by the first analyte sensor. The system may also comprise a second analyte sensor device adapted to provide data indicative of a concentration of the second analyte in the user, the remote control unit comprising an infusion calculator for calculating a bolus or infusion rate on the basis of data supplied by the first and second analyte sensors. The first and second analytes may be blood glucose, in which case the first analyte sensor is a BGM, the second analyte sensor is a CGM, and the remote control unit is adapted to calculate an amount or infusion rate of insulin.

For the different embodiments described above, the medical device or system may comprise releasable mating coupling means for securing the transcutaneous device unit and the process unit to each other to form a substantially rigid connection therebetween.

The present invention also provides a method of using the components comprising the steps of (i) providing a transcutaneous device unit comprising a transcutaneous device and a mounting surface, the transcutaneous device having retracted position relative to the mounting surface, and an extended position in which a distal end projects relative to the mounting surface, (ii) providing a process unit comprising a process assembly adapted to cooperate with the transcutaneous device, (iii) mounting the mounting surface to a skin surface of a subject, (iv) inserting the transcutaneous device into the subject by moving the transcutaneous device from the retracted position to the extended position, and (v) assembling the transcutaneous device unit and the process unit to provide a functional communication between the process assembly and the inserted transcutaneous device.

Corresponding to a further aspect, a medical device comprising a transcutaneous unit and a reservoir unit is provided, wherein the transcutaneous unit comprises transcutaneous means for transporting a fluid through a skin portion of a subject, and a mounting surface adapted for application to the skin of the subject. The reservoir unit comprises a reservoir adapted to contain a fluid drug, the reservoir comprising an outlet allowing the transcutaneous means to be arranged in fluid communication with an interior of the reservoir, and expelling means for, in a situation of use, expelling a fluid drug out of the reservoir and through the skin of the subject via the transcutaneous means. The transcutaneous unit and the reservoir unit further comprise coupling means allowing the reservoir unit to be secured to the transcutaneous unit in the situation of use.

The term "transcutaneous" covers all forms of administration in which a fluid is transported through a portion of the skin, e.g. intradermal or subcutaneous administration. The transcutaneous means may be in the form of a transcutaneous device, a jet injection means or electrodes allowing an ionic agent to permeate from a predetermined site on the surface of skin into the subcutaneous tissue of the subject by using the principle of iontophoresis. For a more thorough discussion of iontophoresis reference is made to US patent 6,622,037 hereby incorporated by reference. Depending on the nature of the transcutaneous means the expelling means may be of different configuration and nature. For example, when one or more hollow infusion needles or cannulas are used, the expelling means may be arranged to force or suck the fluid drug from the reservoir, whereas in the case of iontophoresis the expelling means would be means for applying a current over a set of electrodes, i.e. "driving" means.

Corresponding to a further aspect, a medical device comprising a transcutaneous device unit and a reservoir unit is provided, wherein the transcutaneous device unit comprises a transcutaneous device, and a mounting surface for application to the skin of the subject. The reservoir unit comprises a reservoir adapted to contain a fluid drug, and an expelling assembly adapted for cooperation with the reservoir to expel the fluid drug out of the reservoir and through the skin of the subject via the transcutaneous device. The transcutaneous device unit and the reservoir unit are further adapted to be secured to each other in a situation of use thereby allowing a fluid communication to be established between the reservoir and the transcutaneous device. The transcutaneous device unit and the reservoir unit may comprise releasable coupling means allowing the reservoir unit to be secured to the transcutaneous device unit in a situation of us. Such a medical device comprising two units may also be considered a medical system. The transcutaneous device unit and the reservoir unit may each comprise a housing within which the transcutaneous device respectively the reservoir and the expelling assembly are arranged.

The term expelling assembly covers an aggregation of components or structures which in combination provides that a fluid can be expelled from the reservoir. The expelling assembly may e.g. be a mechanical pump (e.g. a membrane pump, a piston pump or a roller pump) in combination with electronically controlled actuation means, a mechanically driven pump (e.g. driven by a spring), a gas driven pump or a pump driven by an osmotic engine. The expelling assembly may also me in the form of an aggregation of components or structures which in combination provides that a fluid can be expelled from the reservoir when the expelling assembly is controlled or actuated by a controller external to the expelling assembly.

The transcutaneous device (which term also covers the similar terms transcutaneous access device and transcutaneous access tool traditionally used in this technical field) may be in the form of a pointed hollow infusion needle, a micro needle array, or a combination of a relatively flexible *per se* blunt cannula with a pointed insertion needle may provide a pointed transcutaneous device, the insertion needle being retractable after insertion of the blunt portion of the transcutaneous device. In the latter case the portion of the transcutaneous device actually placed in the subject and subsequently retracted by the herein described retraction means does not necessarily comprise a pointed end allowing the combined transcutaneous device to be inserted through the skin, such a pointed end being withdrawn during insertion of the transcutaneous device. The cannula is advantageously soft and flexible relative to the insertion needle which typically is a solid steel needle. In the disclosure of the present invention as well as in the description of the exemplary embodiments, reference will mostly be made to a transcutaneous device in the form of an infusion needle. The length of the transcutaneous device may be chosen in accordance with the actual application, e.g. a hollow steel needle which may be inserted at a substantially right angle relative to the skin surface may have an inserted length of 2-8 mm, preferably 3-5 mm, whereas a cannula which may also be inserted at an oblique angle relative to the skin surface may be somewhat longer, e.g. 4-20 mm.

The mounting surface is adapted for application against the skin of a subject (e.g. user or patient) and may be held in contact with the skin by attaching means external to the mounting surface (e.g. coupling means allowing the medical device to be coupled to a skin mountable device, or an adhesive bandage or a dressing) or by adhesive means provided on the mounting surface. The mounting surface may also be adapted for mounting towards the skin via an interposed component of a skin mountable device, e.g. a skin mountable device may comprise a receiving portion to which the medical device is attached, the transcutaneous device being inserted into the skin through an aperture in the receiving portion.

By the above arrangement different concepts can be realized. For example, by providing at least two different of one of the units, it will be possible to provided two or more combinations, wherein each combination of a transcutaneous device unit and a reservoir unit provides an assembly will have different capabilities as discussed in further detail below. In case the units are provided with releasable coupling means, one of the units can be exchanged with a new or different unit yet allowing the other unit to be re-used, thereby lengthening the operational life of the re-used unit. Thus, the present invention provides in an exemplary embodiment a device in which the components providing the interface with the user is incorpo-

rated in a first unit whereas the components providing the drug delivery *per se* is incorporated in a second unit, this allowing the combined components to be combined or exchanged in a simple, reliable and user-friendly way.

For example, the reservoir unit may be provided with an amount of drug and a delivery pump comprising an energy source allowing the drug to be delivered over e.g. 10 days, whereas the transcutaneous device unit may be provided with a transcutaneous device and an adhesive surface on the mounting surface having an expected (or recommended) operational life of 2 days, this allowing the reservoir unit to be used with 5 transcutaneous device units over a period of 10 days, this considerably lowering the total costs of using the combined device. The reservoir may be pre-filled or adapted to be filled one or more times.

On the other hand, a transcutaneous device unit may be provided with e.g. a needle or a soft cannula, and adhesive means (e.g. of the type used for attaching colostomy bags) allowing the needle unit to be mounted and used over an extended period of time, the reservoir unit having a shorter expected operational life, e.g. when relatively large amounts of drugs have to be infused. Alternatively, different reservoir units with different types of drugs may be used in combination with such a "long-term" mounted needle unit.

For ease of use, the fluid communication between the needle and the reservoir may be established when the needle unit and the reservoir unit are secured to each other, just as the expelling means may be activated when the needle unit and the reservoir unit are secured to each other and de-activated when the units are released from each other. Indeed, one or both of the operations may also be performed manually by the user.

In an exemplary embodiment the expelling assembly comprises a pump having an inlet adapted to be arranged in fluid communication with the outlet of the reservoir, and an outlet adapted to be arranged in fluid communication with the transcutaneous device, thereby allowing the transcutaneous device to be arranged in fluid communication with the interior of the reservoir. By such an arrangement the pump will serve as a suction pump drawing drug from the reservoir which consequently will have to be either collapsible or vented in case a non-collapsible reservoir is used. The expelling assembly may also be in the form of an arrangement adapted to pressurize the reservoir, e.g. an arrangement for driving a piston in a reservoir comprising a displaceable piston. The reservoir unit may comprise more than one reservoir and more than one expelling assembly. For example, a single expelling assembly may be used to expel drug from more than one reservoir, either simultaneously thereby mix-

ing drugs or alternating, or each reservoir may be provided with an expelling assembly which may be connected to a common transcutaneous device or to individual transcutaneous devices, e.g. the transcutaneous device unit may comprise more than one transcutaneous device adapted to be connected to a expelling assembly.

In order to provide an initially sterile flow path through the pump, the flow path may be arranged between the inlet and outlet such that the inlet and outlet seal the interior of the pump and thereby the flow path in an initial sterile state. By this arrangement it will not be necessary to provide the reservoir unit as an entirely sterile unit – indeed, the drug will have to be provided in a sterile state.

In an exemplary embodiment, the reservoir unit is transformable from an initial condition in which there is no fluid communication between the pump and the reservoir to a non-reversible operating condition in which fluid communication is established between the inlet means of the pump and the outlet means of the reservoir when the pump unit is secured to a needle unit for the first time. By this arrangement it is avoided that undesired matter is introduced into the reservoir during re-connection between the pump and the reservoir.

To secure a clean connection between the pump and the reservoir, a separate fluid connector may be arranged within the interior of the pump in the initial condition. Such a fluid connector may comprise a pointed inlet end and an outlet, whereas the inlet of the pump and the outlet of the reservoir may be in the form of two needle- penetratable septa. By this arrangement the pointed end of the fluid connector, e.g. a connection needle, can be moved through the two septa and thus between the initial condition and an operating condition in which fluid communication is established between the interior of the reservoir and the interior of the pump via the fluid connector, the outlet of the fluid connector being arranged in the flow path. Advantageously the fluid connector is moved between its two positions as the reservoir unit is connected to a transcutaneous device unit for the first time. Correspondingly, during such a first connection two fluid communications will be established (between the transcutaneous device of the transcutaneous device and the pump, and between the pump and the reservoir), whereas during subsequent connections only a single new fluid communication will be established (between the transcutaneous device of the transcutaneous device unit and the pump).

In an exemplary embodiment the transcutaneous device comprises a first portion having a pointed distal end, and a second portion in fluid communication with the first portion and hav-

ing a second end. Advantageously the second end of the transcutaneous device is pointed and the outlet means of the pump comprises a needle-penetratable septum allowing a fluid communication to be established between the second end of the transcutaneous device and the interior of the pump, preferably as the two units are connected to each other.

Correspondingly, in a further aspect the present invention provides a pump having an inlet means adapted to be arranged in fluid communication with a fluid supply, and an outlet means, the pump comprising an internal flow path arranged between the inlet and outlet means, the inlet and outlet means sealing the interior of the pump and thereby the flow path in an initial sterile condition, wherein a fluid connection means is arranged within the interior of the pump in the initial condition, the fluid connection means comprising an inlet end and an outlet, whereby the fluid connection means is arranged to be moved between the initial condition and to an operating condition in which the inlet end projects from the pump inlet means, whereby a fluid communication can be established between the fluid supply and the interior of the pump via the fluid connection means and with the outlet of the fluid connection means being arranged in the flow path.

The transcutaneous device unit may be supplied with e.g. a needle projecting from the mounting surface, however, to limit the risk of accidental needle injuries, the pointed end of the transcutaneous device is advantageously moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. Depending on the intended method of mounting the device on the user, the transcutaneous device may be moved between the two positions as the two units are connected to each, as would be appropriate in case the transcutaneous device unit is mounted on the skin of the user before the reservoir unit is connected. However, in case the two units are intended to be connected to each other before assembled units are mounted on the skin of the user, the transcutaneous device unit advantageously comprises user-actuatable actuation means for moving the pointed end of the transcutaneous device between the initial and the extended position.

To prevent inadvertent actuation of the transcutaneous device before the two units are assembled, the transcutaneous device unit may comprise means for blocking the actuation means, the blocking means being released when the transcutaneous device unit and the reservoir unit are secured to each other, thereby allowing the actuation means to be actuated.

To further reduce the likelihood of transcutaneous device injuries, the pointed end of the transcutaneous device may be moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface. Correspondingly, the combined device may comprise user-actuatable retraction means for moving the pointed end of the transcutaneous device between the extended and the retracted position when the retraction means is actuated. To prevent re-use of the transcutaneous device, the transcutaneous device may be permanently locked in its retraced position.

To prevent user-errors the actuation means for introducing the transcutaneous device may in an initial condition cover the retraction means, actuation of the actuation means uncovering the retraction means. For example, the actuation means may be in the form of gripping means (e.g. a strip) which is removed from the device, whereby removal triggers transcutaneous device insertion and at the same time uncovers the retraction for withdrawing the transcutaneous device.

As described above, the expelling assembly may be activated and deactivated when the two units are assembled and disassembled, however, the actuation and retraction means may also be used to activate respectively deactivate the expelling assembly. Just as for the initial connection between the pump and the reservoir, the initial activation of the expelling assembly may result in electronic control means being activated resulting in start of pumping action, whereas subsequent deactivation will only deactivate the actual pump action, the control means still being active (e.g. counting the time since initial activation of the control means).

In the above disclosure of the invention the two units have been described primarily as “unitary” units, however, this is only an exemplary configuration and these two “main” units may in case it is deemed desirable be subdivided into further units. For example, the reservoir unit may be provided with an exchangeable control unit, this allowing different types of control units to be connected to the reservoir unit *per se*. e.g. a first type of control unit may provide a single delivery profile, a second control unit may be programmable to thereby modify the delivery pattern, or a control third unit may comprise means allowing the control unit to communicate with external means. In the latter case the control unit may be controlled using a cordless remote control. Correspondingly, the reservoir may be exchangeable allowing different sizes of reservoirs or different types of drugs to be used.

In a further aspect of the invention, a transcutaneous device unit is provided as described above and being adapted to be used in combination with a reservoir unit as disclosed above. Correspondingly, the invention also provides a reservoir unit as disclosed above, the reservoir unit being adapted to be used in combination with a transcutaneous device unit as disclosed above. In an exemplary embodiment such a transcutaneous device unit may be provided with a hollow needle comprising a pointed distal end with an outlet opening and being adapted to penetrate the skin of a subject, and a pointed proximal end with an inlet opening forming a fluid inlet means, the fluid inlet means being adapted to be arranged in fluid communication with a fluid supply. By this arrangement the needle provides a hydraulically stiff fluid communication between the needle inlet and outlet openings (e.g. made from metal), this allowing early occlusion detection by monitoring a pressure build-up upstream of the needle.

In a yet further aspect, a system is provided comprising a first needle unit and a first reservoir unit as disclosed above in combination with a least one further needle unit or reservoir unit as disclosed above, the further unit(s) having different capabilities than the first units. The different capabilities may relate to any constructional feature of the units, e.g. the type of needle, the type of user-actuatable means, the type of delivery/pump means, or the type of reservoir/drug.

More specifically, in an exemplary embodiment a system is provided comprising a transcutaneous device unit as disclosed above, and a plurality of reservoir units, each comprising a reservoir containing a fluid drug, and an expelling assembly for expelling fluid drug from the reservoir. The transcutaneous device unit and the reservoir units comprise mating coupling means allowing a reservoir unit to be secured to the transcutaneous device unit to provide fluid communication between the reservoir and the transcutaneous device, wherein each combination of a transcutaneous device unit and a reservoir unit provides an assembly having different capabilities. The different capabilities may be realized providing e.g. reservoir units with different amounts of the same drugs, reservoir units with different drugs or variants of a given drug, reservoir units adapted to expel drug at different preset rates, reservoir units adapted to expel at fixed respectively selectable rates. One of the reservoir units may be provided with a processor controlling the expelling assembly and a receiver operatable coupled to the controller for receiving flow instructions from a separate control device and delivering the flow instructions to the processor. The receiver may be a wireless receiver. The reservoir units may further be provided with different input means (e.g. for wireless or non-

wireless connection, or manual input), or different output means (e.g. for wireless or non-wireless connection, different display means, or different alarm means).

In a further exemplary embodiment, a system is provided comprising a plurality of transcutaneous device units as described above, and a reservoir unit comprising a reservoir containing a fluid drug, and an expelling assembly for expelling fluid drug from the reservoir. The transcutaneous device units and the reservoir unit comprise mating coupling means allowing a transcutaneous device unit to be secured to the reservoir unit to provide fluid communication between the reservoir and the transcutaneous device, wherein each combination of a transcutaneous device unit and a reservoir unit provides an assembly having different capabilities. The different capabilities may be realized by providing the transcutaneous device units with different transcutaneous devices such as a hollow subcutaneous needle, a cannula and insertion needle assembly, and a micro needle array, by providing different adhesives, by providing different insertion or retraction means, or by providing different coupling means.

In a yet further exemplary embodiment, a system is provided comprising a transcutaneous device unit comprising a transcutaneous device and a mounting surface adapted for application to the skin of a subject, a reservoir unit comprising a reservoir containing a fluid drug, and at least a portion of an expelling assembly for expelling fluid drug from the reservoir, and a plurality of control units, each comprising a controller for controlling an expelling assembly, each having different capabilities. The transcutaneous device unit and the reservoir unit comprise mating coupling means allowing the reservoir unit to be secured to the transcutaneous device unit to provide fluid communication between the reservoir and the transcutaneous device, and the controller units and the reservoir unit comprise mating coupling means allowing a controller unit to be secured to the reservoir unit to control the expelling assembly, whereby each combination of a transcutaneous device unit, a reservoir unit and a control unit provides an assembly having different capabilities. The control units may have different control functions as described above in respect of a system comprising a plurality of reservoir units. In an alternative configuration the reservoir unit and the transcutaneous device unit may be provided as a unitary structure adapted to cooperate with the control unit.

The present invention also provides a method comprising the steps of providing a transcutaneous device unit comprising a transcutaneous device and a mounting surface, providing a reservoir unit comprising a reservoir adapted to contain a fluid drug, and an expelling assembly for expelling fluid drug from the reservoir, the method comprising the further step of assembling the transcutaneous device unit and the reservoir unit to provide a fluid communi-

cation between the reservoir and the transcutaneous device. The fluid communication between the transcutaneous device and the reservoir may be established when the two units are assembled or it may be established when the assembled device is further actuated, both options being covered by the above definition. The method may comprise the further steps of mounting the mounting surface to a skin surface of a subject, and, after mounting the mounting surface to the skin surface of the subject, actuating the transcutaneous device to establish a fluid communication between the reservoir and the subject.

A further method provides a drug delivery device dispensing a drug at a preset rate, the method comprising the steps of providing a system comprising a transcutaneous device unit comprising a transcutaneous device and a mounting surface adapted for application to the skin of a subject, the system further comprising a plurality of reservoir units, each comprising a reservoir containing a fluid drug, and an expelling assembly for expelling fluid drug from the reservoir at a preset rate, selecting a reservoir unit having a desired preset rate, and assembling the transcutaneous device unit and the selected reservoir unit to provide a fluid communication between the reservoir and the transcutaneous device.

In the above disclosure the present invention has been described with reference to a drug delivery device, however, the concept of the invention can be regarded as a modular system providing a number of advantages. Thus, the transcutaneous device unit may also be in the form of a needle sensor and the “reservoir unit” may correspondingly be in the form of a device adapted to transmit and/or process data acquired via the sensor.

In the above primarily a system comprising a sensor unit and a receiving unit is described, however, the present invention also provides a sensor unit and a receiving unit *per se*, each such unit comprising the features allowing the present invention to be implemented, as well as optionally comprising one or more of the additional features described in detail above. Correspondingly, a medical sensor unit is provided adapted to generate sensor data indicative of a time-dependent body characteristic of a subject, and transmit data to a receiver at intervals determined by an analysis of time-dependent changes in the generated sensor data.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or ac-

tive agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin. Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject. Further, the term needle (when not otherwise specified) defines a piercing member adapted to penetrate the skin of a subject.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with references to the drawings, wherein

figs. 1-11 shows in perspective views the sequences of use for a first embodiment of a drug delivery device,

fig. 12 shows a further embodiment of a reservoir unit,

fig. 13 shows in a non-assembled state a needle unit and a reservoir unit for a further embodiment of a drug delivery device,

fig. 14 shows an exploded view of the needle unit of fig. 13,

fig. 15 shows a perspective view of the needle unit of fig. 13 in a first state,

fig. 16 shows a perspective view of the needle carrier of fig. 14,

fig. 17 shows a perspective view of the needle unit of fig. 13 in a second state,

fig. 18 shows a side view of the needle unit of fig. 13,

fig. 19 shows a further perspective view of the needle unit of fig. 13,

fig. 20 shows perspective view of the interior of the reservoir unit of fig. 13,

fig. 21 shows an exploded view of a further reservoir unit,

fig. 22A shows a schematic overview of a pump connected to a reservoir,

fig. 22B shows an exploded view of a pump assembly,

fig. 22C shows a cross-sectional view of the pump assembly of fig. 22C,

figs. 22D and 22E show partial cross-sectional views of the pump assembly of fig. 22C,

figs. 23A and 23B show in a schematic representation a transcutaneous device in the form of a cannula and insertion needle combination,

fig. 24 shows a perspective view of a further drug delivery device,

figs. 25A-25D show different expelling means suitable for use with the invention,

fig. 26 shows a medical device with a modular reservoir unit,

fig. 27 shows a modular system for a medical device,

figs. 28A-28C show infusion systems comprising delivery device, analyte sensor and remote control unit,

figs. 29A and 29B show a modular medical sensor device in different stages, and

figs. 30A and 30B show analyte curves with data sampling at intervals.

In the figures like structures are mainly identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical” or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

Firstly, with reference to figs. 1-12 an embodiment of a drug delivery device will be described focusing primarily on the directly user-oriented features. The transcutaneous device unit 2 comprises a transcutaneous device in the form of a hollow infusion needle and will thus in the following be termed a needle unit, however, the needle may be replaced with any desirable transcutaneous device suitable for delivery of a fluid drug.

More specifically, fig. 1 shows a perspective view of medical device in the form of a modular skin-mountable drug delivery device 1 comprising a patch-like needle unit 2 and a reservoir unit 5. When supplied to the user each of the units are preferably enclosed in its own sealed package (not shown).

The needle unit comprises a base portion 10 with a lower mounting surface adapted for application to the skin of a user, and a housing portion 20 in which a hollow infusion needle (not shown) is arranged. The needle comprises a first needle portion having a pointed distal end adapted to penetrate the skin of a user, and a second pointed end adapted to be arranged in fluid communication with the reservoir unit. In the shown embodiment the pointed end of the needle is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. Further, the needle is moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface. The needle unit further comprises user-gripable actuation means in the form of a first strip-member 21 for moving the pointed end of the needle between the initial and the second position when the actuation means is actuated, and user-gripable retraction in the form of a second strip-member 22 means for moving the pointed end of the needle between the extended and the retracted position when the retraction means is actuated. As can be seen, the second strip is initially covered by the first strip. The housing further comprises user-actuatable male coupling means 40 in the form of a pair of resiliently arranged hook members adapted to cooperate with corresponding female coupling means on the reservoir unit, this allowing the reservoir unit to be releasable secured to the needle unit in the situation of use. In the shown embodiment the base portion comprises a relatively rigid upper portion 11 attached to a more flexible adhesive sheet member 12 having a lower adhesive surface providing the mounting surface *per se*, the adhesive surface being supplied with a peelable protective sheet. The base portion also comprises a ridge member 13 adapted to engage a corresponding groove on the reservoir unit.

The reservoir unit 5 comprises a pre-filled reservoir containing a liquid drug formulation (e.g. insulin) and expelling means in the form of an electronically controlled pump for expelling the drug from the reservoir through the needle in a situation of use. The reservoir unit has a generally flat lower surface adapted to be mounted onto the upper surface of the base portion, and comprises a protruding portion 50 adapted to be received in a corresponding cavity of the housing portion 20 as well as female coupling means 51 adapted to engage the corresponding hook members 31 on the needle unit. The protruding portion provides the interface between the two units and comprises a pump outlet and contact means (not shown) allowing the pump to be started as the two units are assembled. The lower surface also comprises a window (not to be seen) allowing the user to visually control the contents of the reservoir.

First step in the mounting procedure is to assemble the two units by simply sliding the reservoir unit into engagement with the needle unit (fig. 2). When the hook members properly engage the reservoir unit a "click" sound is heard (fig. 3) signalling to the user that the two units have been properly assembled. If desired, a visual or audible signal may also be generated. Thereafter the user removes the peelable sheet 14 to uncover the adhesive surface (fig. 4) where after the device can be attached to a skin surface of the user, typically the abdomen (fig. 5). Infusion of drug is started by gripping and pulling away the actuation strip 21 as indicated by the arrow whereby the needle is inserted followed by automatic start of the infusion (fig. 6). The needle insertion mechanism may be supplied in a pre-stressed state and subsequently released by the actuation means or the needle insertion may be "energized" by the user. A "beep" signal confirms that the device is operating and drug is infused. The reservoir unit is preferably provided with signal means and detection means providing the user with an audible alarm signal in case of e.g. occlusion, pump failure or end of content.

After the device has been left in place for the recommended period of time for use of the needle unit (e.g. 48 hours) – or in case the reservoir runs empty or for other reasons - it is removed from the skin by gripping (fig. 7) and pulling (fig. 8) the retraction strip 22 as indicated by the arrows which leads to retraction of the needle followed by automatic stop of drug infusion where after the strip which is attached to the adhesive patch is used to remove the device from the skin surface (fig. 9).

When the device has been removed the two units are disengaged by simultaneously depressing the two hook members 31 as indicated by the arrows (fig. 10) allowing the reservoir unit 5 to be pulled out of engagement with the needle unit 2 as indicated by the arrow (fig.

11) which can then be discarded. Thereafter the reservoir unit can be used again with fresh needle units until it has been emptied.

The reservoir unit may be supplied with a fixed basal infusion rate or it may be supplied as an adjustable unit (fig. 12) with adjustment means 55 allowing the infusion rate to be set by a physician and/or the user/patient. The reservoir unit may also be provided with means allowing the control means to be programmed or set electronically (not shown).

The device described with reference to figs. 1-11 may also be used in alternative ways. For example, the needle unit may be mounted to the skin after which the reservoir is attached. Depending on the configuration of the needle unit, it may be possible or prevented that the needle is introduced before the reservoir unit is attached.

Fig. 13 shows a further embodiment of medical device 500 substantially corresponding to the embodiment of fig. 1, the device comprising a patch-like needle unit 502 and a thereto attachable reservoir unit 505.

Fig. 14 shows an exploded perspective view of the needle unit comprising an upper housing portion 510, a needle carrier 520 and a thereto mounted infusion needle 530, an actuation member 540, a release member 550, a lower housing portion 560 and a sheet member 570. The actuation member comprises a user gripable portion 541 and a needle actuation portion 542, and the release member comprises a user gripable portion 551 and a needle retraction portion 552. In the assembled state as shown in fig. 15, the upper and lower housing portions form a housing 503 in which the needle and the needle carrier is mounted, the actuation and release members being operatable connected to the needle carrier with the user gripable portions arranged outside the housing. In contrast to the fig. 1 embodiment does the needle unit not comprise a base plate portion but instead two ridge members 561 extending from the housing, the ridge members and the lower surface of the housing being mounted on the flexible sheet member which is provided with a lower adhesive layer 571 on its lower surface allowing the needle unit to be attached to a skin site of a subject. The sheet member further comprises an opening 572 arranged in register with a lower protrusion 565 provided around the exit aperture for the transcutaneous device, just as the sheet is provided with a large number of small perforations to improve breathability through the sheet. The housing 503 is provided with user actuatable coupling means 511 allowing a reservoir unit to be attached to and released from the needle unit 505, the reservoir unit comprising corresponding mating

coupling means 506 as well as a display 587. The display may indicate e.g. proper function of the unit, the amount of drug in the reservoir or different error conditions.

As seen is the user gripable portion 551 of the release member initially covered by a portion of the actuation member, this reducing the probability that the user erroneously uses the release member instead of the actuation member. Further, the actuation and release members (or portion thereof) may be colour coded to further assist the user to correctly use the device. For example, the actuation member may be green to indicate "start" whereas the release member may be red to indicate "stop".

Fig. 16 shows in perspective the needle carrier 520 with the needle 530 and the needle actuation portion 542 of the actuation member 540. The needle actuation portion comprises two legs 543 allowing it to slide relative to the housing, the legs being arranged through respective openings 563 in the housing. The needle carrier is adapted to be connected to a hinge member 562 of the lower housing portion to thereby allow the needle carrier and thereby the needle to pivot corresponding to a pivoting axis defined by a hinge. In the shown embodiment is the needle carrier in the form a bent sheet metal member, the carrier comprising an upper arm 521 and a lower arm 522 connected to each other by a hinge portion 523 allowing the lower arm to pivot relative to the upper arm and corresponding to the pivoting axis. The lower arm forms a tray in which the hollow infusion needle 530 is mounted (e.g. by welding or adhesive), the needle having a distal pointed portion 531 adapted to penetrate the skin of the subject, the distal portion extending generally perpendicular to the mounting surface of the needle unit, and a proximal portion 532 arranged substantially corresponding to the pivoting axis and adapted to engage a fluid supply. Thus, when a portion of the upper arm is mounted in the housing, the lower arm can pivot between a first retracted position in which the distal portion of the needle is retracted within the housing, and a second extended position in which the distal portion projects relative to the mounting surface. In the shown embodiment the needle carrier provides the drive means for moving the lower arm between the two positions. This may as in the present embodiment be provided by the elastic properties of the sheet material *per se* corresponding to the hinge portion, or alternatively an additional spring may be provided between the two arms to thereby urge them apart. To lock the lower part in an energized, releasable first position, the upper arm is provided with a flexible release arm 526 comprising a catch 527 supporting and arresting the lower arm in its first downwardly biased position, as well as a release portion 528 engaging a ramp surface 544 of the needle actuation portion 542, the catch further comprising an inclined edge portion 529 adapted to en-

gage the lower arm when the latter is moved from its extended to its retracted position as will be described in greater detail below.

To actuate the needle the user grips the flexible strip forming the user gripable portion 541 (which preferably comprises adhesive portions to hold it in its shown folded initial position) and pulls the needle actuation portion 542 out of the housing, the actuation member 540 thereby fully disengaging the housing. More specifically, when the ramp surface 544 is moved it forces the latch 527 away from the lower arm to thereby release it, after which the release portion 528 disengages the ramp allowing the two legs to be pulled out of the housing. As seen in fig. 17, when the actuation member is removed the user gripable portion 551 of the release member is exposed. As for the actuation member, the user gripable portion of the release member preferably comprises adhesive portions to hold it in its shown folded initial position.

In the shown embodiment the release member is in the form of a strip formed from a flexible material and having an inner and an outer end, the strip being threaded through an opening 512 in the housing, the strip thereby forming the user gripable portion 551 and the needle retraction portion 552, the inner end of the strip being attached to the housing and the outer end of the strip being attached to a peripheral portion of the sheet member 570 or, alternatively, a peripheral portion of the housing. In the projection shown in fig. 18 the release member is shown in its initial position, the retraction portion forming a loop 555 arranged below the lower arm of the needle carrier, this position allowing the lower arm to be moved to its actuated position and thereby the needle to its extended position.

When the user decides to remove the needle unit from the skin, the user grips the user gripable portion 551, lifts it away from the housing and pulls it upwardly whereby the loop shortens thereby forcing the lower arm upwardly, this position corresponding to an intermediate release state. By this action the lower arm engages the inclined edge portion 529 of the catch 527 thereby forcing it outwardly until it snaps back under the lower arm corresponding to the position shown in fig. 16. As the actuation member 540 has been removed from the needle unit, the needle carrier is irreversibly locked in its retracted position. When the user further pulls in the release member, the peripheral portion of the sheet member to which the release member is attached will be lifted off the skin, whereby the needle unit with its attached reservoir unit can be removed from the skin, this as shown and described with reference to figs. 7-9.

Advantageously, the actuation and release members may be formed and arranged to communicate with the reservoir unit (not shown). For example, one of the legs of the actuation member may in its initial position protrude through the housing to thereby engage a corresponding contact on the reservoir unit, this indicating to the reservoir unit that the needle unit has been attached, whereas removal of the actuation member will indicate that the needle has been inserted and thus that drug infusion can be started. Correspondingly, actuation of the release member can be used to stop the pump.

In fig. 19 the side of the needle unit 502 which connects to the reservoir unit is shown. In addition to the two ridge members 561 and the user actuatable coupling means 511 the needle unit comprises further structures which connects to and/or engages the reservoir unit to provide a functional interface with the reservoir unit. More specifically, the needle unit comprises a fluid inlet provided by the pointed proximal portion 532 of the needle projecting from the needle unit and adapted to engage a fluid outlet of the reservoir unit, an actuator 515 projecting from the needle unit and adapted to engage and actuate a fluid connector in the reservoir unit (see below), and first and second contact actuators 548, 558 adapted to engage corresponding contacts on the reservoir unit. The first contact actuator is provided by the distal end of one of the legs 543 of the needle actuator projecting through an opening in the housing, and the second contact actuator is provided by a hinged portion of the housing connected to the needle retraction portion 552 of the release member 550. When the needle unit is first connected to the reservoir unit both contact actuators will protrude from the housing and engage the corresponding contacts on the reservoir unit thereby indicating that that a needle unit has been connected. When the needle is actuated the first contact actuator will be withdrawn and thereby disengage the corresponding contact on the reservoir unit to start pump actuation. When the needle is retracted the second contact actuator will pivot and disengage the corresponding contact on the reservoir unit to stop pump actuation.

Fig. 20 shows the reservoir unit with an upper portion of the housing removed. The reservoir unit comprises a reservoir 760 and an expelling assembly comprising a pump assembly 300 and control and actuation means 580, 581 therefore. The pump assembly comprises an outlet 322 for connection to a transcutaneous access device (e.g. the needle 530) and an opening 323 allowing an internal fluid connector to be actuated, see below. The reservoir 560 is in the form of prefilled, flexible and collapsible pouch comprising a needle-penetratable septum adapted to be arranged in fluid communication with the pump assembly, see below. The shown pump assembly is a mechanically actuated membrane pump, however, the reservoir

and expelling means may be of any suitable configuration, e.g. as disclosed with reference to figs. 25A-25D.

The control and actuation means comprises a pump actuating member in the form of a coil actuator 581 arranged to actuate a piston of the membrane pump, a PCB or flex-print to which are connected a microprocessor 583 for controlling, among other, the pump actuation, contacts 588, 589 cooperating with the contact actuators on the needle unit, signal generating means 585 for generating an audible and/or tactile signal, a display (not shown) and an energy source 586. The contacts are preferably protected by membranes which may be formed by flexible portions of the housing.

In fig. 21 an exploded view of the reservoir unit 505 of fig. 13 is shown, the unit comprising an upper housing member 507, a lower housing member 508 with a transparent area 509 and grooves 504 to receive the ridge members 561 extending from the needle unit, a flexible reservoir 760 with a rounded edge portion 762 on which a septum member 761 is mounted, a pump assembly 300 with actuator and a circuit board (not shown) arranged above the reservoir and comprising electronic components for controlling actuation of the pump. The upper and lower housing members comprise reservoir mounting means in the form of opposed upper and lower ridge portions 780 (the lower not seen) adapted to engage and mount the reservoir in the housing. Each ridge portion comprises a central cut-out portion 781 adapted to engage the septum member on its opposed surfaces when the housing members are assemble thereby locking the reservoir in place within the housing. The degree of locking will be determined by the pressure exerted on the septum member, the elastic properties of the septum member and the friction between the ridge and the septum member. On each side of the cut-out portion the ridge portions comprise a straight portion 782 which may aid in mounting the reservoir in the housing. The straight portions may engage the initially prefilled reservoir to help lock it in place, however, as the reservoir is emptied and flattens this grip may lessen. In contrast, the engagement with the septum is adapted to properly hold the reservoir in place as the reservoir is emptied. The straight portions may also be adapted to pinch and fully flatten the reservoir thus serving as an additional mounting means. Additional mounting means (not shown) may engage and grip the reservoir at other locations, e.g. along the welded edges 765.

With reference to fig. 22A a schematic overview of a pump connected to a reservoir is shown, the pump comprising the following general features: a fluid connection 391 to reservoir a reservoir 390, a safety valve 392, inlet and outlet valves 393, 394, a pump chamber

395 with an associated piston 396, and an outlet 397. The arrows indicate the flow direction between the individual components. When the piston is moved downwards (in the drawing) a relative negative pressure will build up inside the pump chamber which will cause the inlet valve to open and subsequently fluid will be drawn form the reservoir through the open primary side of the safety valve. When the piston is moved upwards (in the drawing) a relative overpressure will build up in the pump chamber which will cause the inlet valve to close and the outlet valve and the safety valve to open whereby fluid will flow from the pump chamber through the outlet valve and the secondary side of the safety valve to the outlet. As appears, in normal operation the safety valve allows fluid passage during both intake and expelling of fluid and is thus "passive" during normal operation. However, in case the reservoir is pressurized (as may happen for a flexible reservoir) the elevated pressure in the reservoir will be transmitted to both the primary side of the safety valve and, via the pump chamber, the secondary side of the safety valve in which case the pressure on the primary side of the safety valve will prevent the secondary side to open.

In fig. 22B an exploded view of a pump assembly 300 utilizing the pump principle depicted in fig. 22A is shown, the pump assembly (in the following also referred to as a pump) being suitable for use with the reservoir units of figs. 1-13. The pump is a membrane pump comprising a piston-actuated pump membrane with flow-controlled inlet- and outlet-valves. The pump has a general layered construction comprising first, second and third members 301, 302, 303 between which are interposed first and second membrane layers 311, 312, whereby a pump chamber 341 is formed by the first and second members in combination with the first membrane layer, a safety valve 345 is formed by the first and third members in combination with the first membrane layer, and inlet and outlet valves 342, 343 are formed by the second and third members in combination with the second membrane layer (see fig. 22C). The layers are held in a stacked arrangement by an outer clamp 310. The pump further comprises an inlet 321 and an outlet 322 as well as a connection opening 323 which are all three covered by respective membranes 331, 332, 333 sealing the interior of the pump in an initial sterile state. The membranes are penetratable or breakable (e.g. made from paper) by a needle or other member introduced through a given seal. The outlet further comprises a self-sealing, needle-penetratable septa 334 (e.g. of a rubber-like material) allowing the pump to be connected to an outlet needle. As shown in fig. 22C a fluid path (indicated by the dark line) is formed between the inlet 321 (see below) and the inlet valve 342 via the primary side of the safety valve 345, between the inlet valve, pump chamber 345 and the outlet valve 343, and between the outlet valve and the outlet 322 via the secondary side of the safety valve, the fluid paths being formed in or between the different layers. The pump also comprises a

piston 340 for actuating the pump membrane, the piston being driven by external driving means (not shown).

The pump further comprises a fluid connector in the form of hollow connection needle 350 slidably positioned in a needle chamber 360 arranged behind the connection opening, see fig. 22D. The needle chamber is formed through the layers of the pump and comprises an internal sealing septum 315 through which the needle is slidably arranged, the septum being formed by the first membrane layer. The needle comprises a pointed distal end 351, a proximal end on which is arranged a needle piston 352 and a proximal side opening 353 in flow communication with the distal end, the needle and the piston being slidably arranged relative to the internal septum and the chamber. As can be appreciated form fig. 22D the needle piston in its initial position is bypassed by one or more radially placed keyways 359. These are provided in order to allow steam sterilisation and to vent the air otherwise trapped when the fluid connector is moved forward in the needle chamber.

The above-described pump assembly may be provided in a drug delivery device of the type shown in figs. 1-20. In a situation of use where the reservoir unit is attached to a needle unit the proximal end 532 of the infusion needle is introduced through the outlet seal and septum 334 of the pump, and the actuator 515 (see fig. 19) is introduced through the connection membrane 333. By this action the connection needle is pushed from its initial position as shown in fig. 22D to a actuated position as shown in fig. 22E in which the distal end is moved through the inlet membrane 331 and further through the needle-penetratable septum of a nearby located reservoir, this establishing a flow path between the reservoir and the inlet valve via the proximal opening 353 in the needle. In this position a seal is formed between the needle piston and the needle chamber.

As appears, when the two units are disconnected, the proximal end 532 of the infusion needle is withdrawn from the pump outlet whereas the connection needle permanently provides fluid communication between the pump and the reservoir.

In the above described embodiments, the transcutaneous device has been in the form of a unitary needle device (e.g. an infusion needle as shown or a needle sensor (not shown)), however, the transcutaneous device may also be in the form of a cannula or a sensor in combination with an insertion needle which is withdrawn after insertion thereof. For example, the first needle portion may be in the form of a (relatively soft) infusion cannula (e.g. a Teflon ® cannula) and a there through arranged removable insertion needle. This type of cannula

needle arrangement is well known from so-called infusion sets, such infusion sets typically being used to provide an infusion site in combination with (durable) infusion pumps.

Thus, figs. 23A and 23B show in a schematic representation how a cannula and insertion needle combination can be arranged within a housing 601 of in a given medical device 600 (partly shown), e.g. an infusion device or an infusion set. More specifically, the medical device comprises a transcutaneous assembly 650 comprising a combination of a relatively soft cannula 651 (which e.g. may be of the soft "Teflon®" type) carried by a lower member 653 and a pointed insertion needle 661 (e.g. made from medical grade stainless steel) slidably arranged within the cannula and carried by an upper member 663, both members being mounted to allow axial displacement of the cannula respectively the insertion needle. The cannula comprises a proximal inlet (not shown) allowing it to be or to be arranged in fluid communication with a fluid source. The medical device further comprises a base plate 620 with an opening 621 for the cannula as well as a release member 622. The lower member comprises an elastomeric seal 652 through which the insertion needle is arranged. The cannula and the insertion needle may be straight or curved dependent upon how the two members are mounted in the device, e.g. arcuate corresponding to a pivoting axis or straight corresponding to linear movement as illustrated. The upper member comprises a coupling member 667 locking the members together in an initial position with distal end of the insertion needle extending from the distal opening of the cannula as shown in fig. 23A, and the base plate comprises coupling member 657 for locking the lower member in an extended position with distal end of the cannula extending through the opening in the base plate (see fig. 23B). Between the housing of the device and the upper member a first spring 668 is arranged biasing the upper member upwards. Correspondingly, the device also comprises a second spring 658 biasing the lower member upwardly. The medical device further comprises a gripping tab 676 and a pulling member 677 corresponding to the embodiment shown in fig. 1.

In a situation of use the assembly is moved downwardly, either manually or by a releasable insertion aid, e.g. a spring loaded member acting through an opening in the housing (not shown) whereby the cannula with the projecting insertion needle is inserted through the skin of a subject. In this position the lower member engages the coupling member 657 to thereby lock the cannula in its extended position, just as the coupling member 667 is released by the release member 622 thereby allowing the upper member to return to its initial position by means of the first spring.

When the user intends to remove the delivery device from the skin surface, the user grips the gripping portion of the tab and pulls it in a first direction substantially in parallel with the skin surface, by which action the flexible strip 677 releases the coupling member 657 from the lower member whereby the lower member and thereby the cannula is retracted by means of the second spring. When the cannula has been withdrawn from the skin, the user uses the now unfolded tab to pull off the entire delivery device from the skin surface, for example by pulling the tab in a direction away from the skin surface.

In fig. 24 an embodiment of a device adapted for the latter mounting procedure described with reference to figs. 1-12 is shown (i.e. mounting the needle unit first).

More specifically, fig. 24 shows a perspective view of medical device in the form of a drug delivery device 100 comprising a needle housing 110, a base member 130 with a lower mounting surface 133 adapted for application to the skin of the subject, and a separate pump unit 150. In the shown embodiment the base member comprises a relatively rigid upper portion 131 attached to a more flexible adhesive patch member 132 having a lower adhesive surface providing the mounting surface *per se*. The needle housing may be formed integrally with the base member or attached thereto as a separate unit, the two elements in combination forming a platform unit. In the shown embodiment the needle unit comprises a housing 111 within which a hollow needle 112 is pivotally arranged.

The housing comprises first and second openings (or windows) covered by first and second cover means. In the shown embodiment the first cover means is in the form of a needle penetratable rubber membrane 121 and the second cover membrane is in the form of a breakable paper sheet allowing components to be introduced into the interior of the housing. The paper sheet is penetratable to sterilizing gases, the paper sheet, the rubber membrane and the housing in combination providing a sterility barrier for the encapsulated needle portion.

The needle comprises a first needle portion 113 having a first pointed end adapted to penetrate the skin of the subject, the first needle portion extending generally perpendicular to the mounting surface, and a second needle portion 114 in fluid communication with the first needle portion via an intermediate needle portion 115 and having a second pointed end, the second needle portion being arranged substantially in parallel with the mounting surface. The needle is connected to the housing by a mounting member 117 allowing the needle to pivot corresponding to an axis defined by the second needle portion, whereby the needle is move-

able between an initial sterile position in which the first needle portion is retracted relative to the mounting surface, and a second position in which the pointed end of the first needle portion projects through the rubber septum and relative to the mounting surface. The housing also comprises a biasing member 118 biasing the needle towards the initial position. Often, the "downstream" portion of a needle (here: the first portion) is referred to as the distal portion, and the "upstream" portion of a needle (here: the second portion) is referred to as the proximal portion.

The reservoir (or pump) unit 150 comprises a housing in which a reservoir and expelling means are arranged. The reservoir is adapted to contain a liquid drug (e.g. prefilled or adapted to be filled by a user) and comprises an outlet means in the form of a protruding needle penetratable septum 155 adapted to be arranged in fluid communication with the second needle portion. The expelling means (not shown) is adapted for in a situation of use to expel a drug out of the reservoir and through the skin of the subject via the hollow needle. The pump unit further comprises a ramp member 156 arranged next to the reservoir outlet. The reservoir and expelling means may be of any suitable configuration, e.g. as disclosed with reference to figs. 25A-25D.

The mounting platform comprises a receiving portion, the receiving portion and the pump unit comprising mating coupling means 160 allowing the pump unit to be secured to the platform unit. The mating coupling means may be releasable allowing a durable or multi-use pump unit to be attached a number of times to a disposable platform unit.

In a situation of use, the platform unit is mounted on the skin of a user (e.g. by adhesive means arranged on the mounting surface) and the pump unit is attached and locked to the platform unit by sliding it into engagement therewith substantially in parallel with the mounting surface. During the latter operation the protruding septum and the ramp member is moved into engagement with the needle, thereby breaking the paper barrier cover 122, during which operation fluid communication is established between the second needle portion and the reservoir, just as the needle is pivoted from its initial to its second position, the first pointed needle end thereby penetrating the rubber membrane and the skin of the user.

After the pump unit has been connected and the needle introduced subcutaneously, the pump can be started. This may happen either automatically as the two units are connected or by separate user-actuatable starting means, e.g. a start button (not shown).

In an alternative embodiment (not shown), the second needle portion may be fixedly (i.e. non-rotationally) attached to the mounting member 117, the intermediate needle portion 115 being elastically bend as it is forced downwardly by the ramp member 156. In such an arrangement the biasing member 118 may be dispensed with.

In the above-described embodiments a delivery device has been described comprising a flexible reservoir in combination with an example of an expelling means. However, the reservoir and the expelling means may be of any type which would be suitable for arrangement within a skin-mountable drug delivery device. Further, as the needle of the present invention also may be in the form of a needle sensor, the interior of the medical device may comprise sensor means adapted to cooperate with the needle sensor.

In figs. 25A-25E examples of expelling means suitable for use with the present invention are shown schematically, however, these are merely examples, just as the shown arrangement of the individual components not necessarily are suitable for direct application in the above shown delivery devices. More specifically, fig. 25A shows a pump arrangement comprising a drug-containing cartridge 1010 forming a reservoir and having a distal closure member 1011 allowing a needle to be connected, and a piston 1015 slidingly arranged there within, a flexible toothed piston rod 1020 (for example as disclosed in US patent 6,302,869), an electric motor 1030 which via a worm-gear arrangement 1031 drives the piston rod to expel drug from the cartridge, the motor being controlled by control means 1040 and the energy for the control means and the motor being provided by a battery 1050 (although the “battery” often is a single electric cell, the normal term battery is used also for such a cell in the following). The pump may be activated when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device.

Fig. 25B shows a pump arrangement comprising a drug-containing cartridge 1110 having distal and proximal closure members 1111, 1112, and a piston 1115 slidingly arranged there within, gas generating means 1120 in fluid communication with the interior of the cartridge via conduit 1121 for driving the piston to expel drug from the cartridge, the gas generating means being controlled by control means 1140 and the energy for the control means and the gas generation being provided by a battery 1150. The pump may be activated as indicated above. A detailed disclosure of such gas generating means for a drug delivery device can be found in e.g. US patent 5,858,001.

Fig. 25C shows a pump arrangement comprising a drug-containing cartridge 1210 having distal and proximal closure members 1211, 1212, and a piston slidingly 1215 arranged there within, an osmotic engine 1220 in fluid communication with the interior of the cartridge via conduit 1221 for driving the piston to expel drug from the cartridge. The osmotic engine comprises a first rigid reservoir 1225 containing a salt-solution and a second collapsible reservoir 1226 containing water, the two reservoirs being separated by a semi-permeable membrane 1227. When supplied to the user, the fluid connection 1228 between the second reservoir and the membrane is closed by a user-severable membrane (e.g. a weak weld) which, when severed, will allow the osmotic process to start as water is drawn from the second reservoir through the membrane and into the first reservoir. The pump may be activated as indicated above. A detailed disclosure of the osmotic drive principle can be found in e.g. US patent 5,169,390.

Fig. 25D shows a pump arrangement comprising a drug-containing flexible reservoir 1310 arranged within a rigid fluid-filled secondary reservoir 1311 in fluid communication with a primary reservoir 1320 through a conduit 1330 comprising a flow restrictor 1331. The primary reservoir is in the form of a cartridge with a moveable piston 1321 and contains a viscous drive fluid. A spring 1340 is arranged to act on the piston to drive fluid from the first to the second reservoir thereby expelling drug from the flexible reservoir when the latter is connected to an infusion needle (not shown). The flow rate will be determined by the pressure generated by the spring in the drive fluid, the viscosity of the drive fluid and the flow resistance in the flow restrictor (i.e. bleeding hole principle). The pump may be activated by straining the spring or by releasing a pre-stressed spring, either when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached from the delivery device. An example of this principle used for drug infusion is known from DE 25 52 446. In an alternative configuration, the drug reservoir may be pressurized directly to expel the drug via a flow restrictor, e.g. as disclosed in US patent 6,074,369.

In fig. 26 is shown a medical device 900 corresponding to the embodiment of figs. 1-11, however, the reservoir unit has a modular design comprising a “durable” control unit 910 adapted to be mounted on a reservoir unit 920 comprising a reservoir and an expelling assembly controllable by the control unit through contacts 921. The transcutaneous device unit 930 may be the same as in figs. 1-11. The transcutaneous device unit and the reservoir unit comprise mating coupling means (931) allowing the reservoir unit to be secured to the transcutaneous device unit to provide fluid communication between the reservoir and the transcutaneous device, and the controller unit and the reservoir unit comprise mating coupling means (917,

921) allowing the controller unit to be secured to the reservoir unit to control the expelling assembly. The control unit may comprise one or more of the following features: a vibrator, a RF transmitter, a RF receiver, a display, a bolus button 918 (as shown) or other user input means, a back-up battery, a memory. Further, the control unit may be adapted to provide a fixed flow rate or it may be programmable (e.g. via a remote control) to provide a given rate or a given profile. The different control units may also be used with different reservoir units (e.g. comprising different drugs or different amounts of drugs), or with different needle units (e.g. comprising a needle or a soft cannula). As stated above, the controller may be used as a durable device by the user, however, (simpler) versions of the controller may come pre-attached to a reservoir unit and be used as a means to provide a varity of disposable devices.

Fig. 27 shows a modular system comprising a number of different types of control units in addition to a basic needle patch unit 930 and a basic reservoir unit 920. A remote controller 940 may be used in combination with some of the control units. The control unit may be in the form of a remotely controllable unit 911 which can only be controlled from a remote controller. A variant 912 thereof may add a bolus button allowing the user to take a bolus of drug without having to use the remote controller. The control unit may be provided as a varity of preprogrammed control units 913, each providing a fixed flow rate as indicated on the unit. Such a unit is intended for use without a remote controller and may include a display 919 as shown. A programmable control unit 914 may also be provided, this allowing e.g. a medical practitioner to program the control unit for an individual patient. A dummy 915 represents any of the disclosed control units in combination with a reservoir unit and a needle unit.

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In the above disclosure of preferred embodiments of the present invention a system has been described comprising a medical device 900 used in combination with a remote controller, however, the medical device of the present invention (e.g. a medical device comprising a transcutaneous unit and a reservoir unit or a sensor device comprising a sensor unit and processor unit adapted to transmit and/or process data acquired via the sensor) may also be used in combination with other and further components to form other systems.

For example, the medical device may be used in combination with one or more sensing devices including a sensor adapted to be used in determining a concentration of an analyte of the user. For the treatment of diabetes and to assist in the controlled infusion of insulin, a sensing device may be adapted to measure a blood glucose level in the user. To determine

the blood glucose level of a person suffering from diabetes, two types of devices may be used.

The traditional blood glucose meter (BGM) is normally used manually a given number of times each day and is based on the application of a small amount of blood to a test strip 821, 831 (see fig. 28A) which is then subsequently placed in the BGM which then supplies a blood glucose value on its display. Traditionally this value was used to check that the blood glucose value was within a desired range, however, it may also be entered into a bolus calculator (also termed a bolus estimator) which will then e.g. recommend a correction bolus to be injected or infused. An early example of a bolus calculator is the "B-D Insulin Dosage Computer" which can also be used to calculate a meal bolus on the basis of user-entered meal information. A bolus calculator may also be incorporated into a drug delivery device, e.g. as shown in US patents 5,665,065 and 6,554,798 or US 2004-0068230, or it may be incorporated into a remote controller for a drug delivery device as shown e.g. in US 2005/0022274 or US 2005/0065760 (also showing that a BGM may be incorporated in the remote controller), which are hereby all incorporated by reference.

In addition to a BGM blood glucose values may also be provided using a continuous blood glucose meter (CGM) which provides continuous or quasi-continuous (e.g. every five minute) blood glucose values. A CGM may be implantable or non-implantable based on e.g. a transcutaneous sensor, a non-transcutaneous sensor or micro-dialysis using a small cannula, and often comprises an external portion attached to the skin of the user by adhesive, the sensor and the external portion forming a sensor unit. The external portion comprises sensor electronics adapted to process and/or transmit the "raw" sensor data supplied from the sensor being indicative of the determined concentration of the analyte in the user. For example, the sensor data may be transmitted to a further unit by wire or wirelessly for further processing, or they may be processed in the external portion of the sensor unit to determine a concentration of the analyte (e.g. glucose) in the user. These values may then be displayed by the sensor unit and/or transmitted to a further unit by wire or wirelessly, where it can be displayed, stored and/or used for further processing. The values supplied from or via the CGM may be used by a bolus estimator for calculating an estimated amount of drug (e.g. insulin) to be infused into the body of the user based upon the received data or they may be used in a closed-loop system for adjusting a basal rate infusion of a drug. Preferably, also BGM values are supplied to the bolus estimator or system in order to adjust for any sensor drift. The bolus or closed-loop calculator may be part of a drug delivery device or it may be part of a remote control unit from which commands are then transmitted to the delivery de-

vice. In the following and with reference to figs. 28A-28C a number of exemplary systems 800, 801, 802 will be described using one or more sensor devices for determining blood glucose, however, other types of sensors for determining the concentration of other analytes may be used. In the below examples the remote control unit is used to collect BGM/CGM data and to calculate and transmit bolus instructions to the delivery device, however, the remote control unit is preferably used as the main user interface between the delivery device and the user allowing the user to e.g. program the delivery device with a given basal rate profile and to change such a profile, to program a bolus amount and the form thereof, and receive information from the delivery device (e.g. by detection of an occlusion). The remote unit may also serve as a storage device for storing information in respect of infusion history (e.g. basal rate and bolus infusions), alarms, personal information (e.g. for preferred types of meals to be used in bolus calculations) and to send data to an external device such as a PC or expert system. In the below examples a drug delivery device 810, 815 is shown as a modular device assembled from subunits, however, the devices may also be of unitary construction and adapted for either disposable or durable use.

Example 1: A medical drug delivery device 810 comprising a transcutaneous device unit 811 and a reservoir unit 811 as disclosed above is provided in combination with a BGM 820 and a wireless remote control unit 830 comprising a processor and an infusion calculator, thereby forming system 800. On basis of blood glucose values and/or values entered into the system by a user via a keyboard 831 (e.g. in respect of a meal) a bolus is calculated and when accepted by the user it is transmitted to the drug delivery device which then infuses the bolus. The BGM data may be entered into the remote unit manually, they may be transmitted from the BGM to the remote unit or the BGM may alternatively be integrated into the remote unit. The CGM shown in fig. 28A is not used in this system.

Example 2: A medical drug delivery device 810 comprising a transcutaneous device unit and a reservoir unit as disclosed above is provided in combination with a BGM 820, a CGM 840 and a wireless remote control unit 830 comprising a processor and an infusion calculator, thereby forming system 800. Data is transmitted from the CGM to the remote unit where they are used in conjunction with BGM data and optionally other data to calculate a bolus or a change in an actual basal rate infusion profile. When a bolus or profile change is calculated it may be transmitted automatically to the drug delivery device (closed loop) or it may be displayed to the user for acceptance (open loop). The BGM data may be entered into the remote unit manually, they may be transmitted from the BGM to the remote unit or the BGM

may be integrated into the remote unit. The data supplied from the CGM and BGM may be raw sensor data or processed data representing a blood glucose value.

Example 3: A medical drug delivery device 810 comprising a transcutaneous device unit and a reservoir unit as disclosed above is provided in combination with a BGM 820, a CGM 840 and a wireless remote control unit 830 comprising a processor and an infusion calculator, thereby forming system 801. Data is transmitted from the CGM to the delivery device and from the delivery device to the remote unit. This arrangement may be advantageous when the distance between the sensor unit and the delivery device is small and when the delivery device is provided with a memory, this allowing CGM data to be transmitted to the remote unit "in bulk", e.g. every hour, this improving energy efficiency. Otherwise the system may be provided and used as described in example 2.

Example 4: A medical drug delivery device 815 comprising a transcutaneous device unit and a reservoir unit as disclosed above is provided in combination with a BGM 820, a CGM 816 and a wireless remote control unit 830 comprising an infusion calculator, thereby forming system 802. In contrast to examples 2 and 3, the CGM is formed integrally with the delivery device. Advantageously a transcutaneous sensor 817 is formed as part of the transcutaneous device unit and the sensor electronics adapted to process and/or transmit the sensor data is formed as part of the reservoir unit. The sensor may be replaced together with the transcutaneous device or independently thereof. Otherwise the system may be provided and used as described in example 3.

Example 5: A medical drug delivery device comprising a transcutaneous device unit and a reservoir unit as disclosed above is provided in combination with a BGM and/or a CGM, the reservoir unit being adapted to receive BGM/CGM data (e.g. wirelessly) and comprising a bolus calculator. The bolus calculator may use the BGM/CGM to calculate a recommendation as described above in examples 1 or 2, or it may calculate and implement a bolus or change of infusion profile.

In the above examples, when a separate medical sensor device is used (e.g. a CGM sensor), such a sensor device may comprise a sensor unit and a processor unit, the sensor unit comprising: a transcutaneous sensor device, a mounting surface adapted for application to the skin of the subject, the processor unit comprising: a processor adapted to transmit and/or process data acquired via the sensor, wherein the sensor unit and the processor unit are adapted to be secured to each other in a situation of use to thereby form a unitary device.

Turning to fig. 29 a sensor unit 850 is shown, comprising a transcutaneous device 851 in the form of a needle-formed sensor 852 in combination with an insertion needle 853, and a mounting surface 855 adapted for application to the skin of the subject. After the sensor unit has been placed on a skin surface the combined transcutaneous device is inserted transcutaneously by the user where after the insertion needle is withdrawn, this leaving the sensor in place. Finally the user attaches the process unit 860 thereby establishing contact between the needle sensor and the circuitry of the process unit. The process unit comprises a processor 861 adapted to transmit and/or process data acquired via the sensor device as well as a power source 862. A further example of sensor insertion can be found in US patents 5,568,806 and 6,809,653, which are hereby incorporated by reference, also disclosing technical information in respect of communication between a medical sensor and an external device.

In the above examples, it is described that sensor data is transmitted to a receiving device such as a wireless remote control unit 830 or a medical drug delivery device or unit 815. The most straightforward way to design a communication protocol between such two units is to have the two devices communicate at regular intervals, e.g. each second. This way the data points are equidistant thereby providing a discrete sampling pattern which can easily be extrapolated into a continuous sensor reading allowing the receiving device to display a nice curve over the data, e.g. on the display of the remote control unit. However, if the data does not change much, there is a lot of unnecessary data transmission and thus waste of energy which may be an important issue for a small skin-mountable unit such as a CGM unit for which long battery life (or a small battery) is an important design parameter for the user of the system. On the other hand, if the data changes very fast, the data transmitted will be inaccurate, i.e. missing important data. Thus, in accordance with an aspect of the present invention, a communication protocol may be used where data are transmitted from the sensor unit when the value has changed more than a predetermined amount. In the case of a glucose sensor transmitting to a remote control unit, this predetermined amount could reflect a clinically significant change in the measured value and/or a change outside the inherent inaccuracy of the measurements. If it is desired to make sure that the devices are still working and in range, this could be accompanied by a timeout function, forcing transmission after another predefined time.

In figs. 30A and 30B a random curve is depicted showing variations in a measured (or calculated) value V for a body analyte, e.g. blood glucose, as a function of time t. In fig. 30A data is transmitted at an equidistant rate to a receiving unit whereas in fig. 30B data is transmitted

at intervals determined by actual variations in the measured or calculated values. When the two figures are compared, it appears that there are fewer samples in fig. 30B, however, there are more samples when the signal changes substantially. The advantage of the algorithm depends on the selected threshold value and the nature of the signal – less fluctuating signal gives a bigger advantage. In the example above, fig. 30A requires 13 samples and fig. 30B 10 samples, yet provides a better resolution.

To save energy in both the transmitting and receiving device, the system may comprise a telemetry system in which sensor data are transmitted during synchronized, pre-selected transmission respectively receiving windows of time, i.e. the transmitter and receiver are not energized in the periods between the transmission/receiving windows. Looking at fig. 30B it appears that in order to be able to receive data at a higher rate, the receiving window has to be open at short intervals, however, in a relatively large device unit such as a remote control unit comprising a display a larger battery can be fitted. Still, if energy consumption is an issue in the receiving device unit (e.g. for a skin-mountable pump unit 810) it may be relevant to reduce energy consumption also in the receiving device. For example, the sensor unit may be adapted to detect periods with only minor variations in the measured level of a given analyte, and correspondingly instruct the receiving unit to open the receiving at longer intervals, e.g. every 5 minutes instead of every 1 minute. To further reduce energy consumption in the units, the length of periods between transmitting and/or receiving windows may be programmable, this allowing e.g. a slower update during the night.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

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CLAIMS

1. A medical system (800) comprising a sensor unit (840) and a receiving unit (830), the sensor unit being adapted to generate sensor data indicative of a time-dependent body characteristic of a subject, and transmit data to the receiver unit at intervals determined by an analysis of time-dependent changes in the generated sensor data, the receiving unit being adapted to receive sensor data at a non-predetermined rate.

2. A system as in claim 1, wherein the receiving unit comprises a display for graphically displaying sensor data related information as a function of time.

3. A system as in claim 1, wherein the receiving unit is adapted to generate estimated sensor data values for time intervals at which no sensor data has been received from the sensor unit.

4. A system as in claim 2 or 3, wherein the receiving unit is adapted to display a continuous graphical representation of sensor data related information.

5. A system as in claim 1, further comprising a telemetry system in which sensor data can be transmitted during synchronized, pre-selected transmission respectively receiving windows of time.

6. A system as in claim 5, wherein periods of time between receiving windows are controlled by the sensor unit and determined by an analysis of the time-dependent changes in the generated sensor data.

7. A system as in claim 5, wherein the period of time between receiving and/or transmitting windows can be selected for one or more individual periods.

8. A system as in claim 1, wherein the sensor unit is adapted to store sensor data values in a memory and transmit the stored values to the receiving unit at a desired point of time.

9. A system as in claim 1, wherein the receiving unit is adapted to transmit instructions to a drug delivery device.

10. A system as in claim 1, wherein the receiving unit comprises a drug delivery device.

11. A system as in claim 9 or 10, wherein the receiving unit is adapted to use received sensor data to calculate delivery parameters for use in the drug delivery device.

12. A system as in any of claims 1-11, wherein the sensor unit comprises a transcutaneous sensor adapted to provide an analyte dependent signal.

13. A system as in any of claims 1-11, wherein the sensor unit comprises a sensor adapted to detect electrical occurrences in the subject.

14. A system as in any of claims 1-13, wherein the sensor unit provides continuous or quasi-continuous data representative of a body characteristic of a subject

15. A medical sensor unit adapted to generate sensor data indicative of a time-dependent body characteristic of a subject, and transmit data to a receiver at intervals determined by an analysis of time-dependent changes in the generated sensor data.

16. A method of operating a medical system, comprising the steps of:

(a) providing a sensor unit (840) and a receiving unit (830), the sensor unit being adapted to generate sensor data indicative of a time-dependent characteristic of a subject,

(b) transmitting data to the receiving unit at intervals determined by an analysis of time-dependent changes in the generated sensor data,

wherein the receiving unit is adapted to receive sensor data at a non-predetermined rate.

Fig. 1

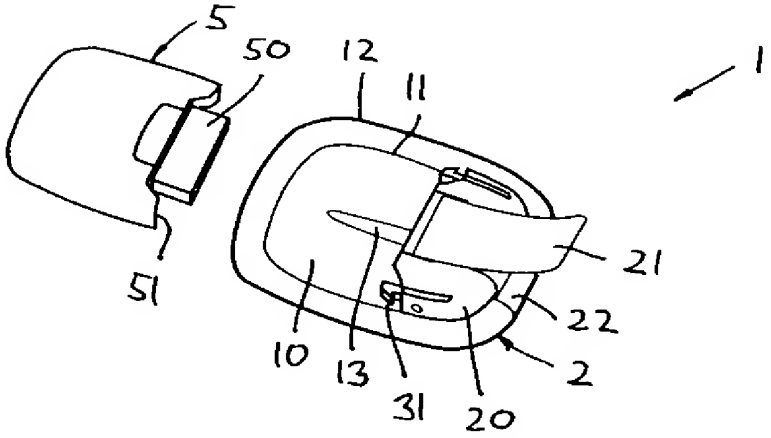


Fig. 2

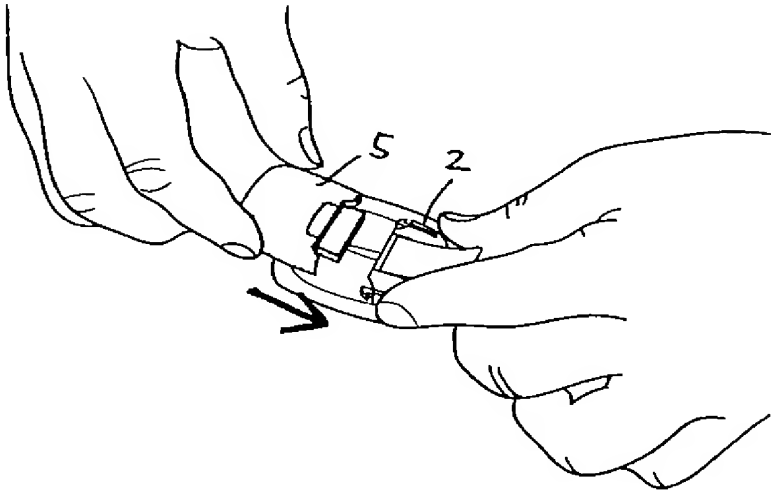


Fig. 3

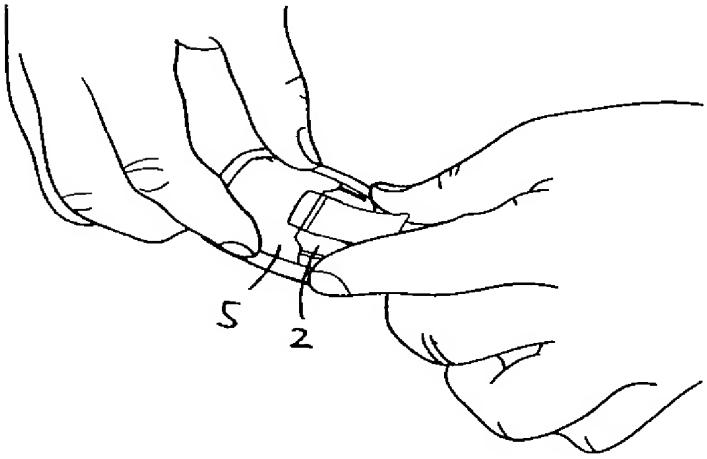


Fig. 4

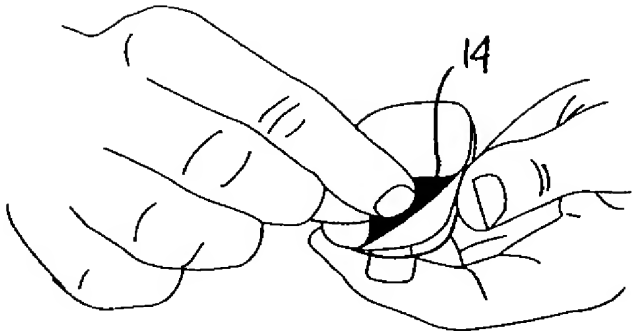


Fig. 5

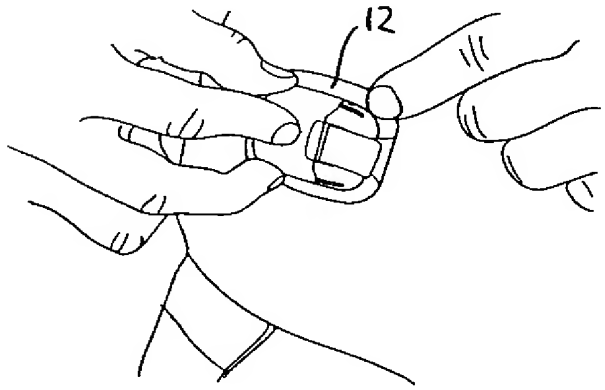


Fig. 6

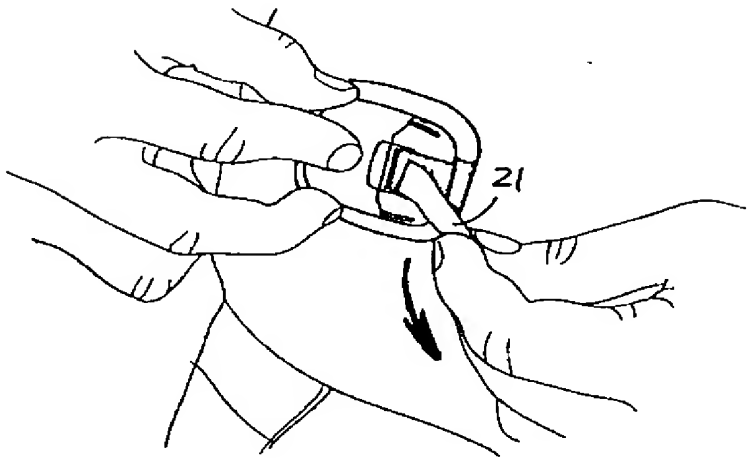


Fig. 7

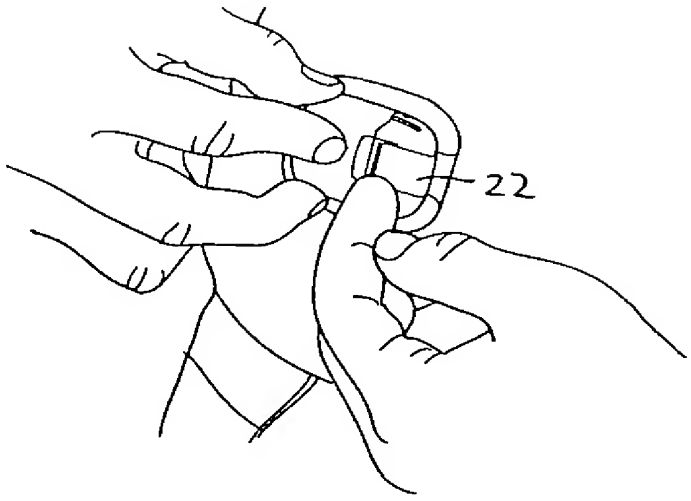


Fig. 8

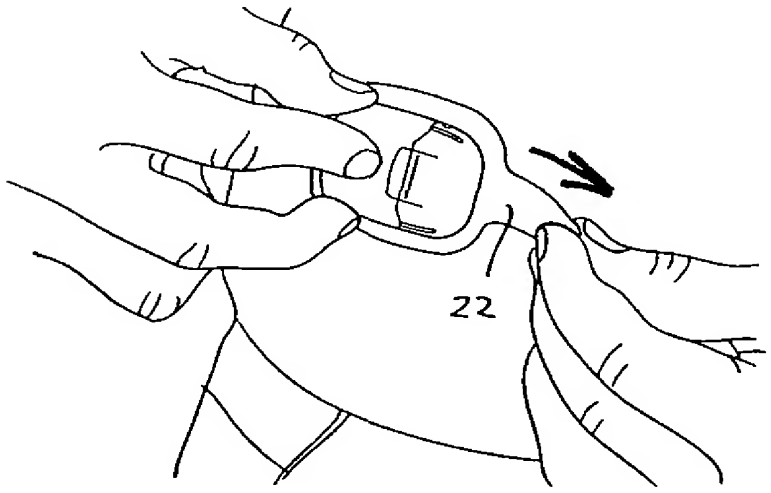


Fig. 9

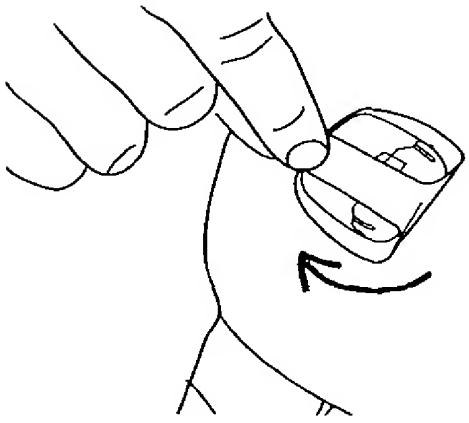


Fig. 10

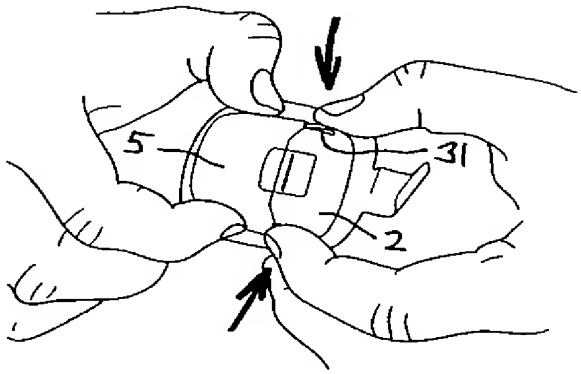


Fig. 11

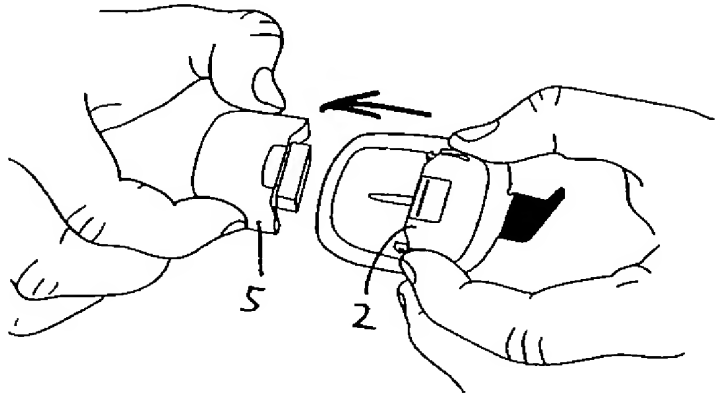


Fig. 12

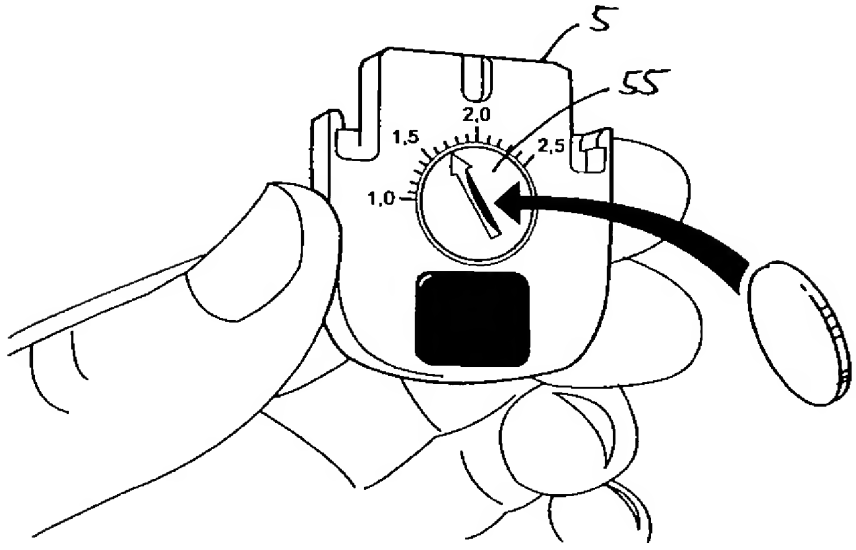
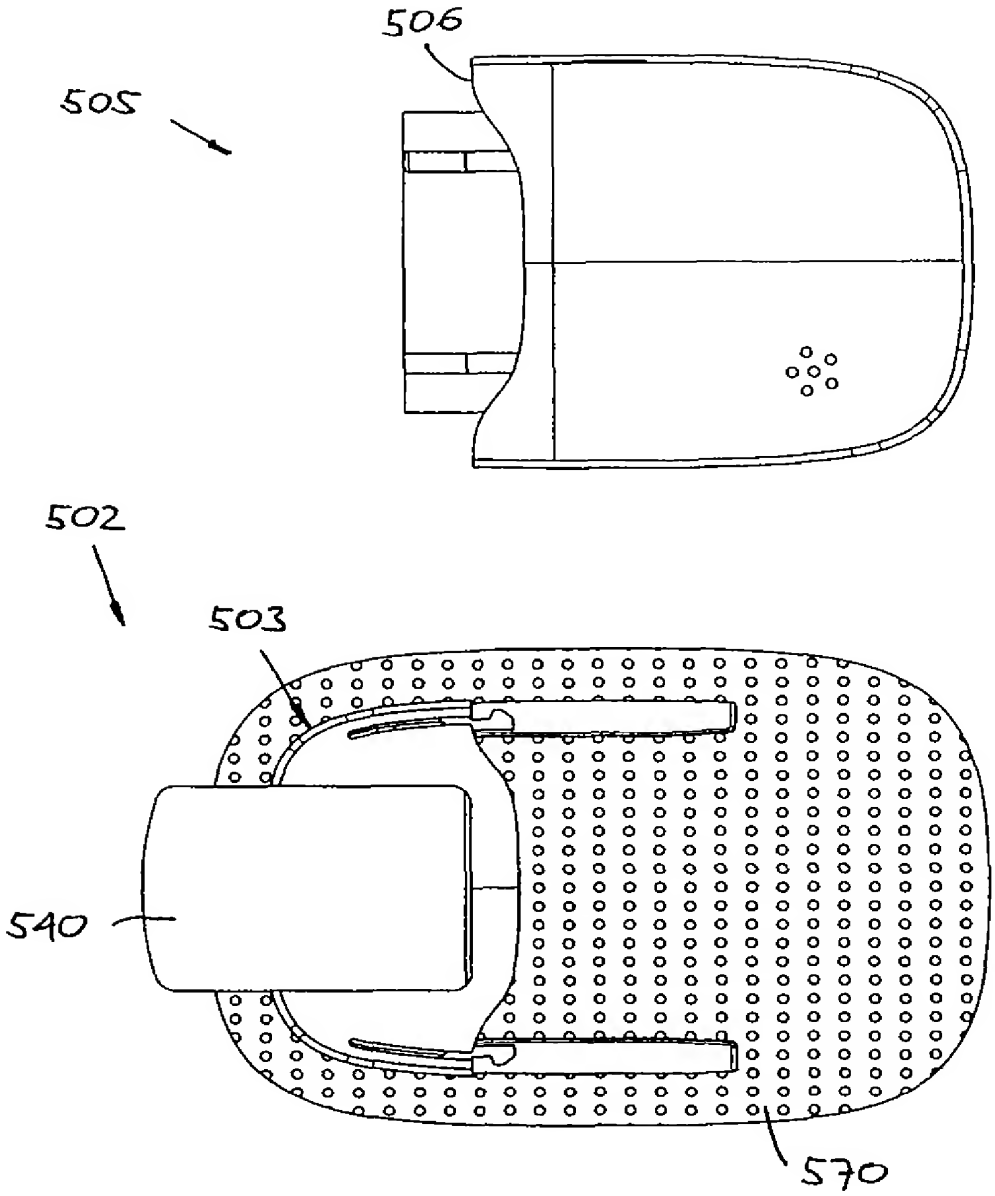


Fig. 13



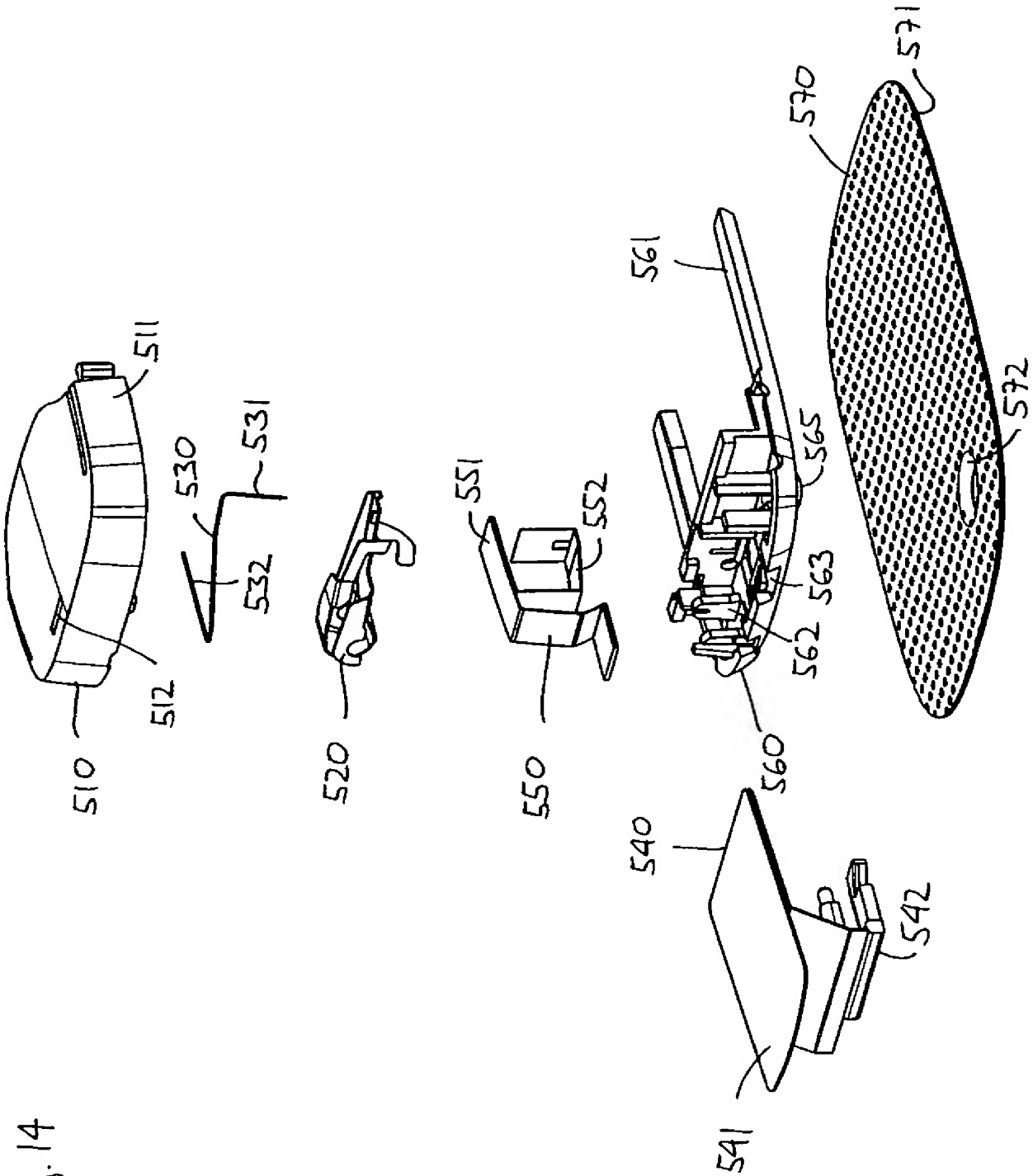

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Fig. 14

Fig. 15

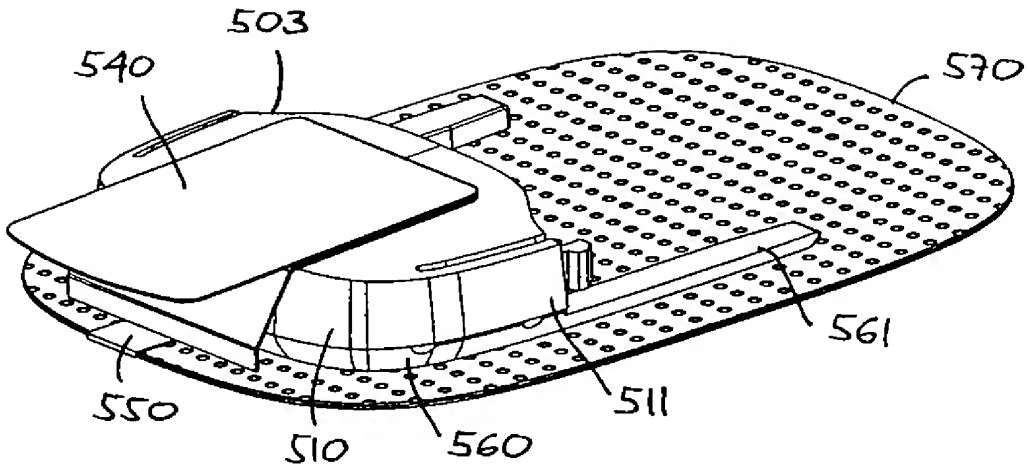
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Fig. 16

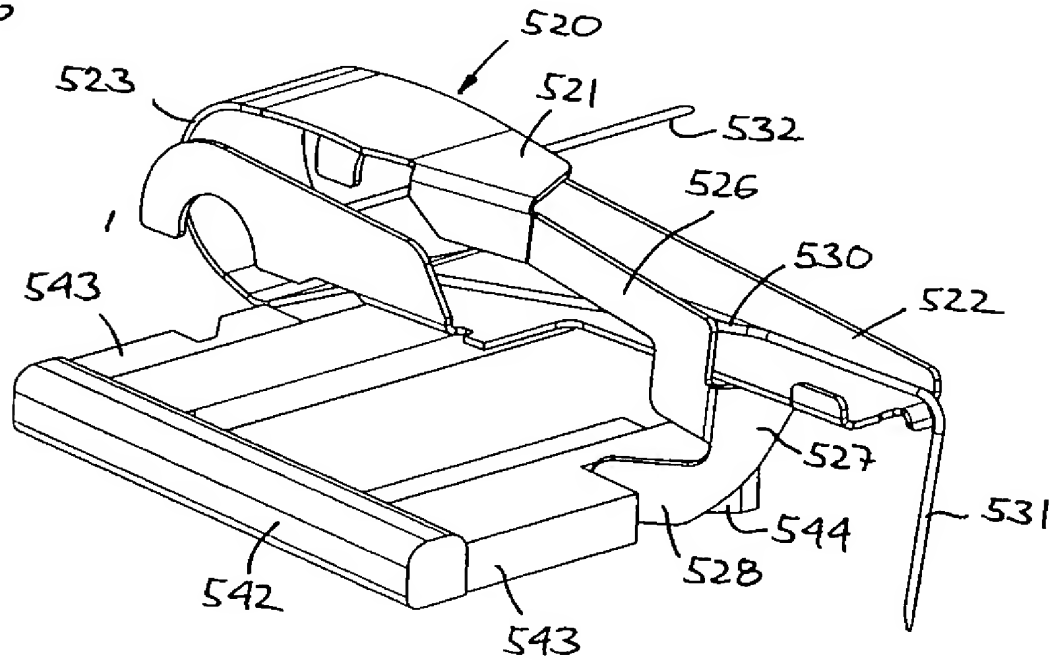
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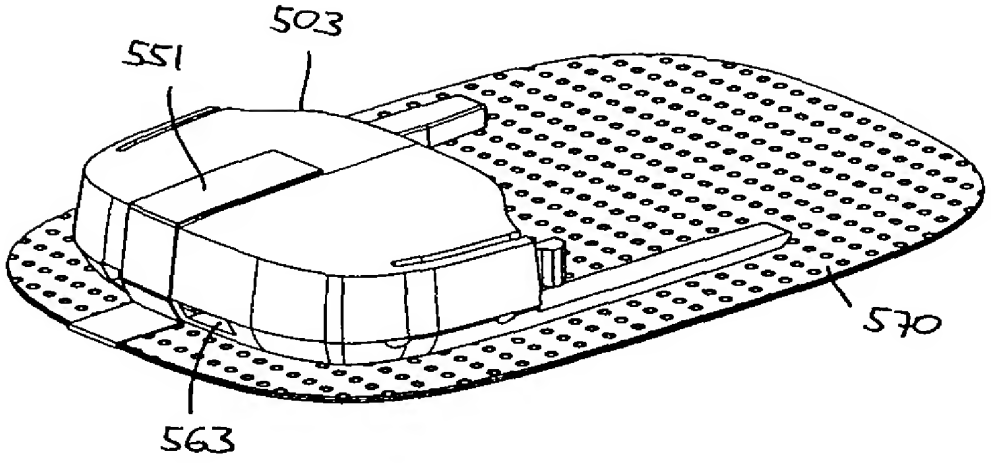
Fig. 17



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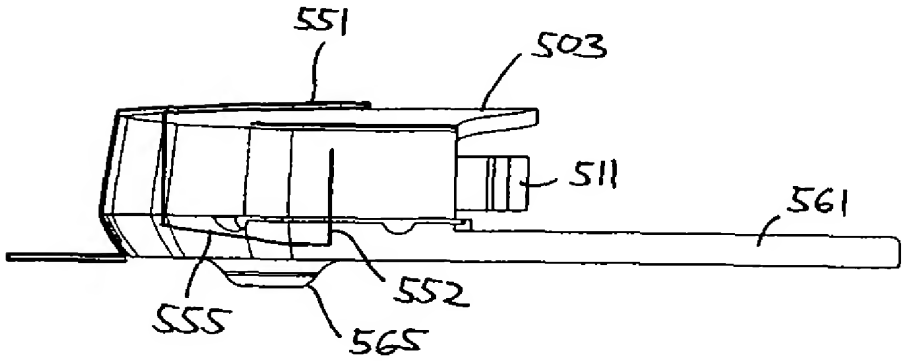

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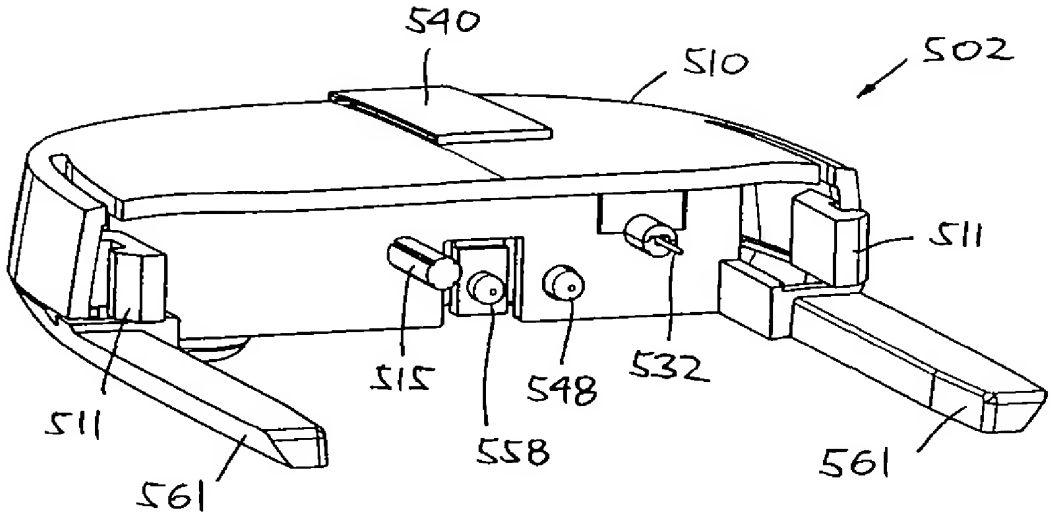
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Fig. 20

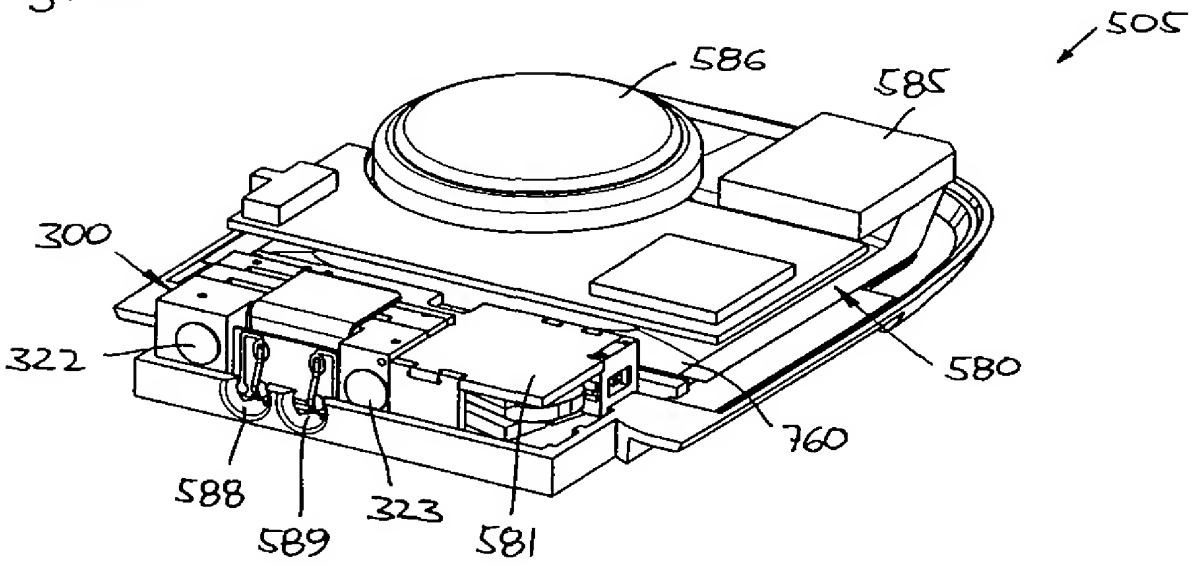
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Fig. 21

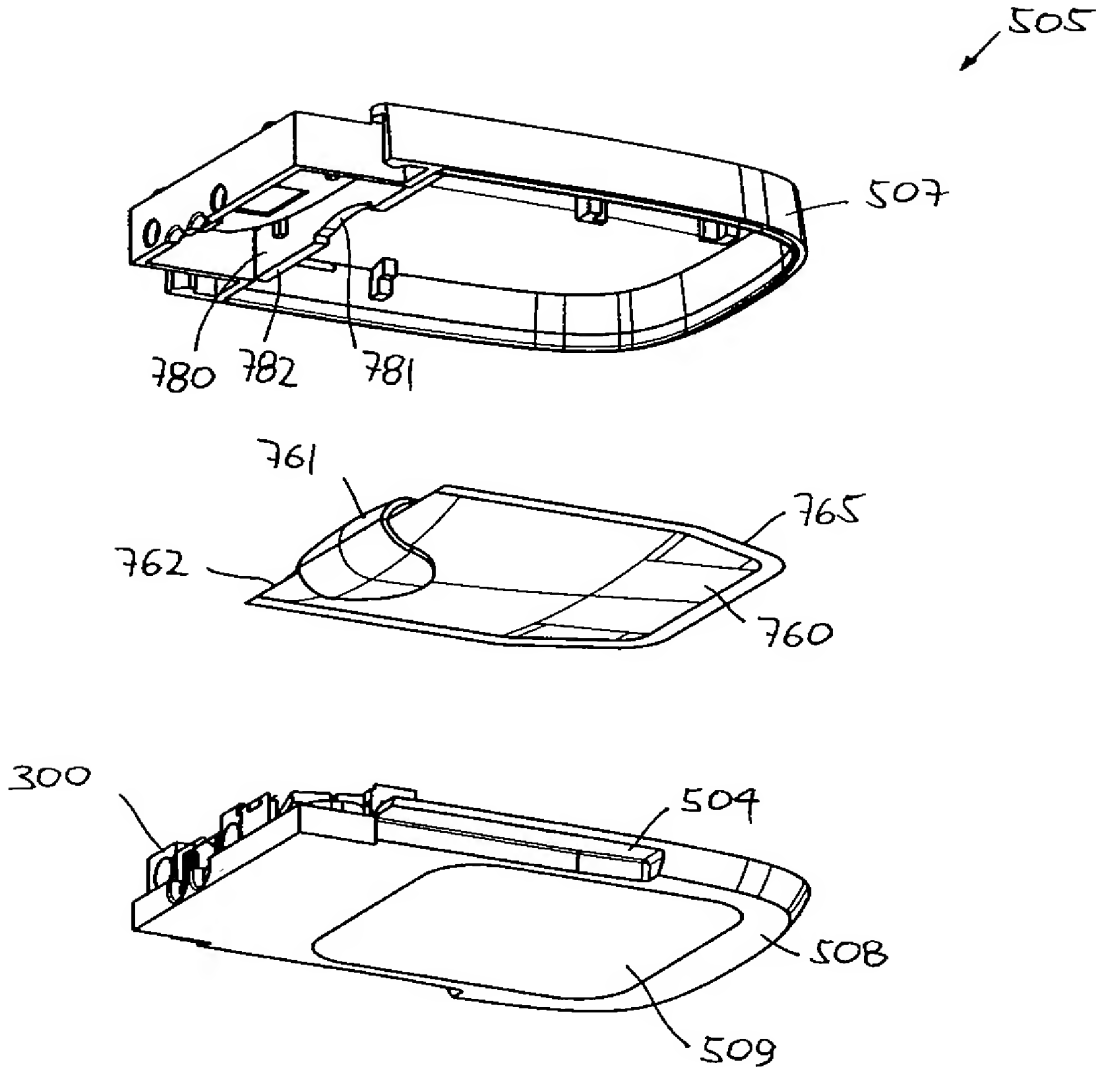

Fig. 22A

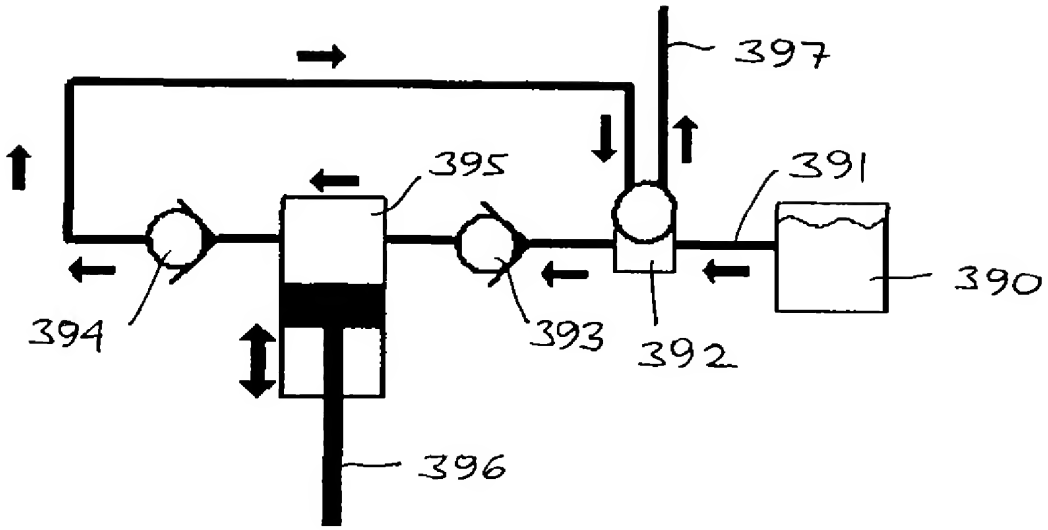

Fig. 22B

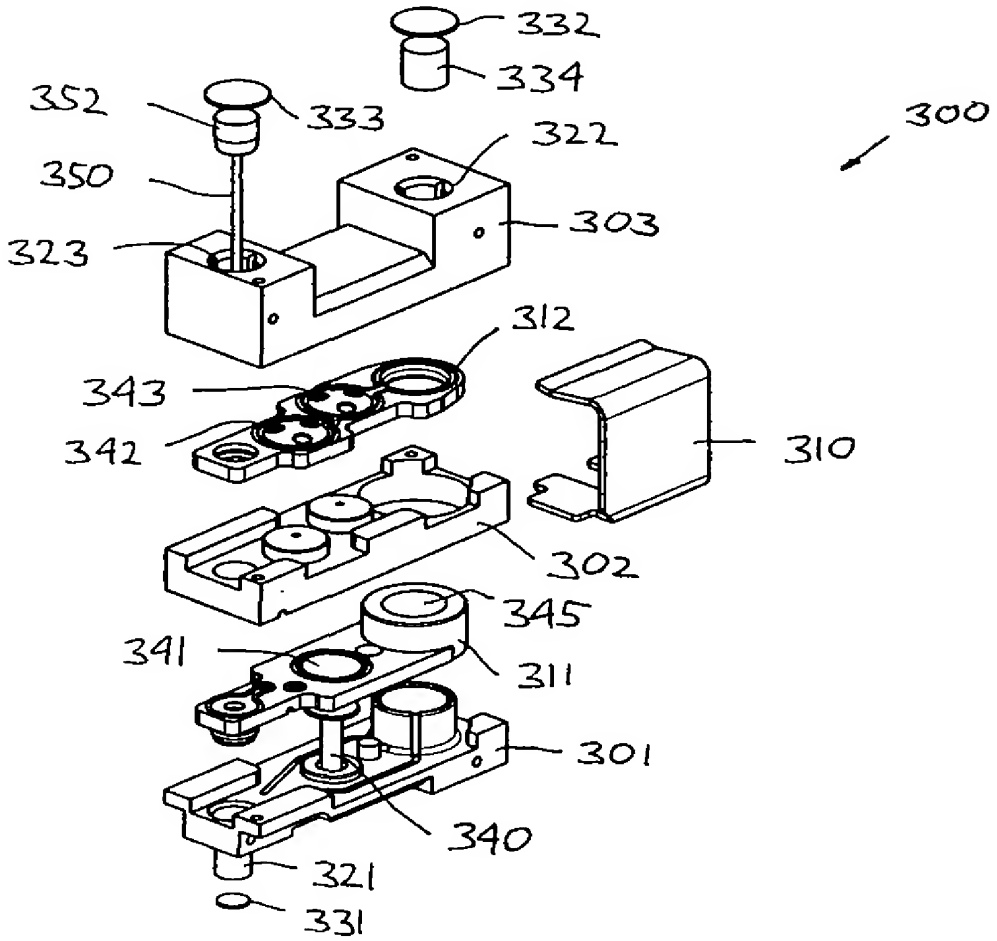

Fig. 22C

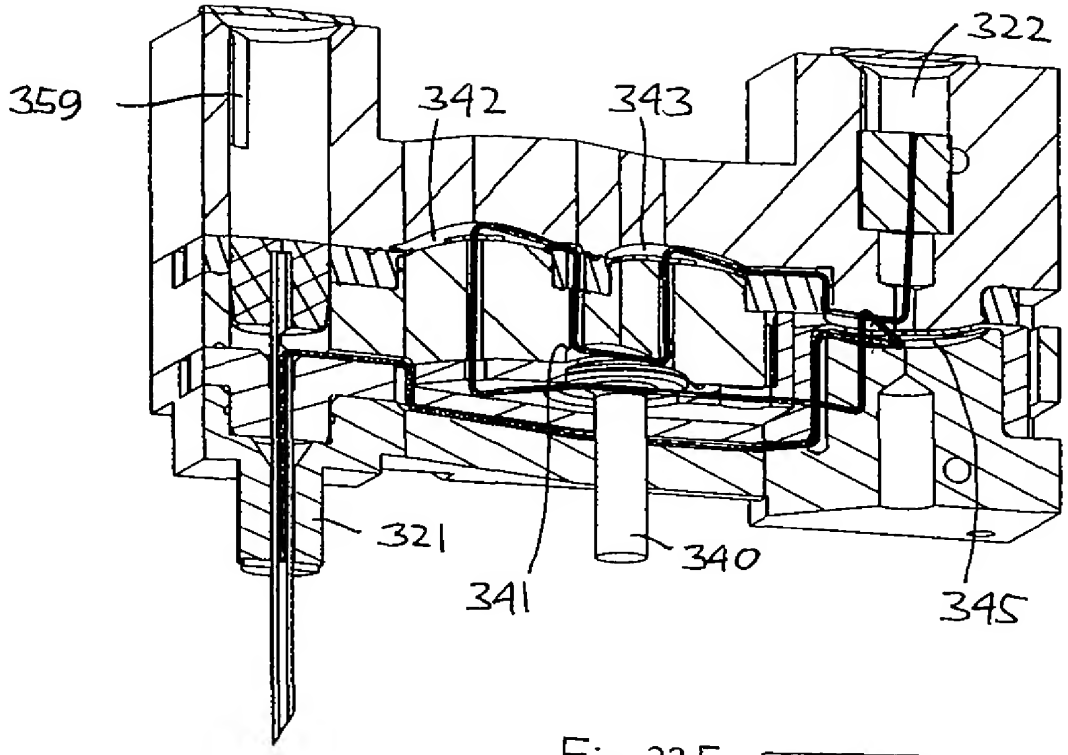

Fig. 22D

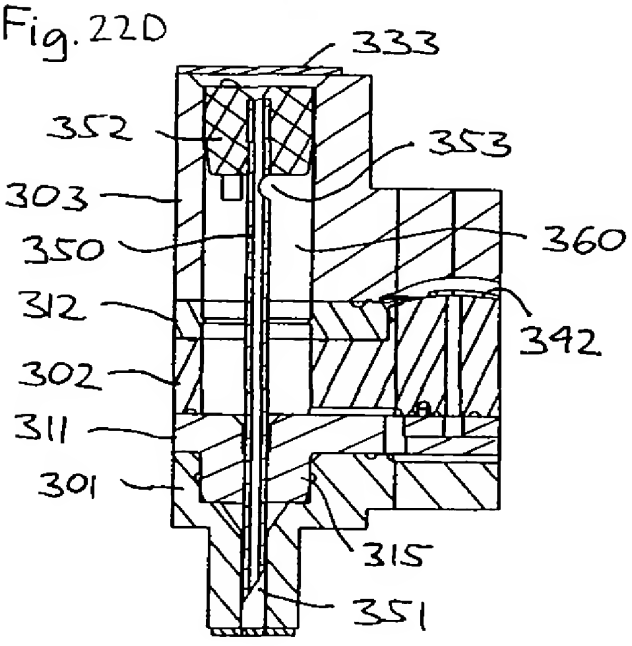

Fig. 22E

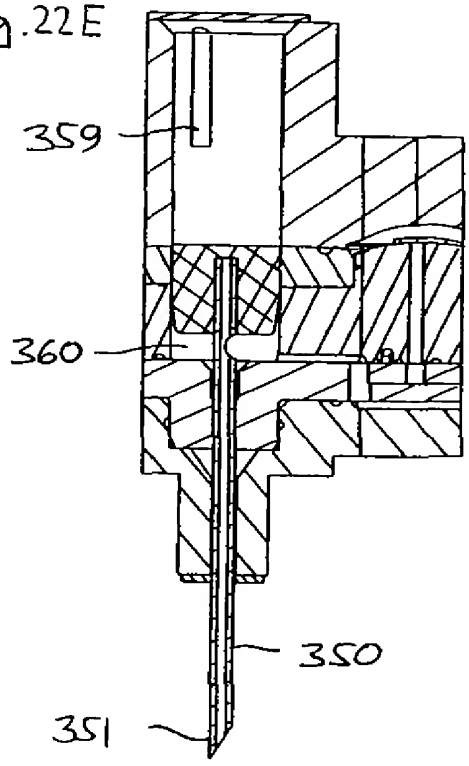

Fig. 23A

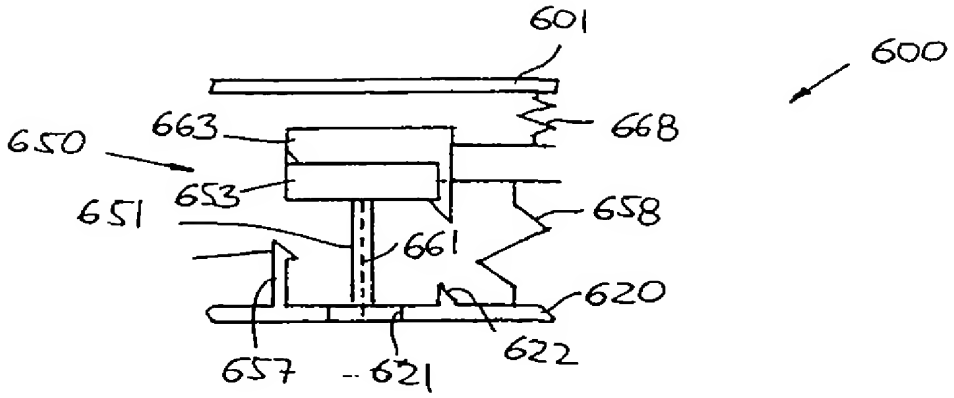

Fig. 23B

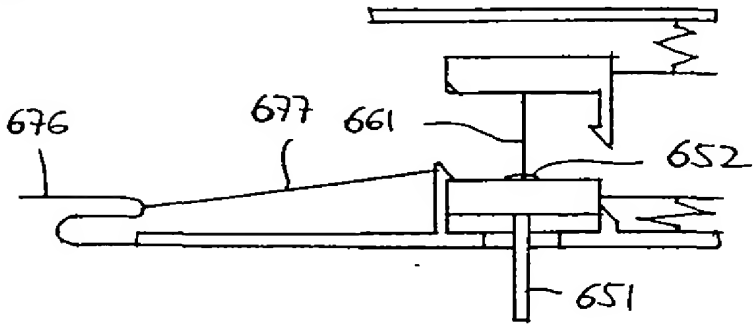

Fig. 24

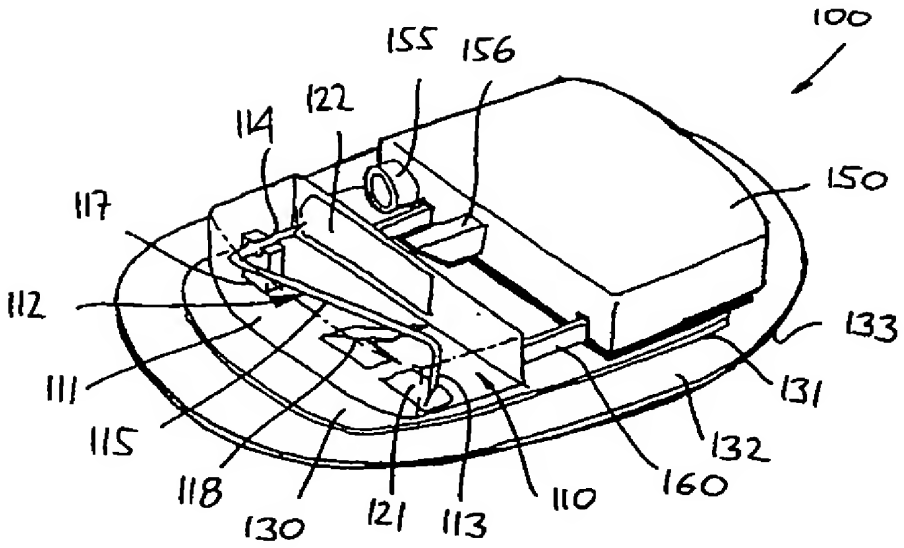
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Fig. 26

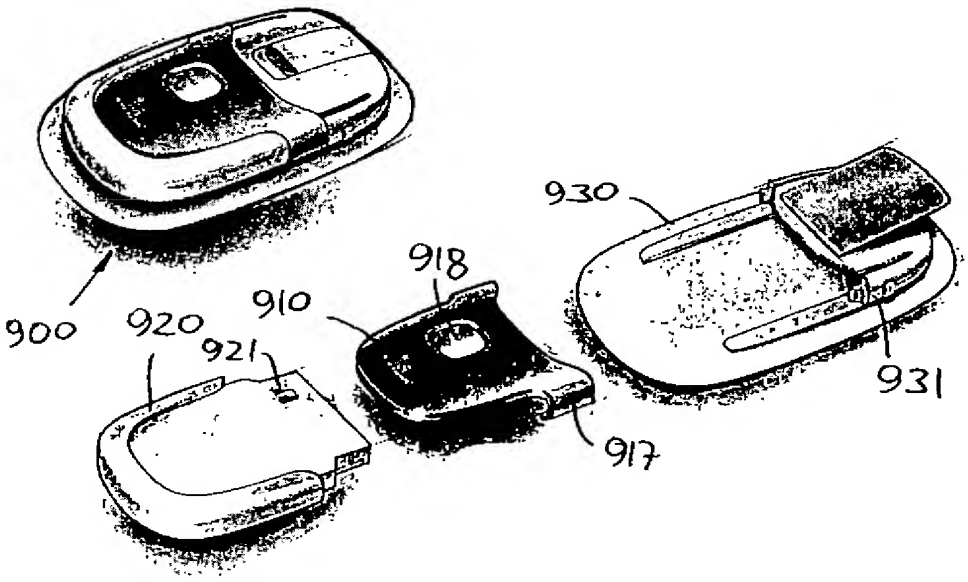
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Fig 25A

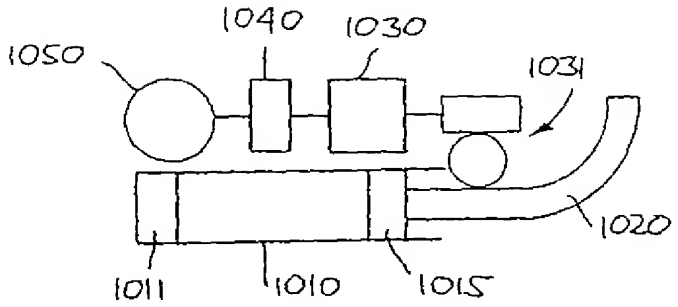


Fig. 25B

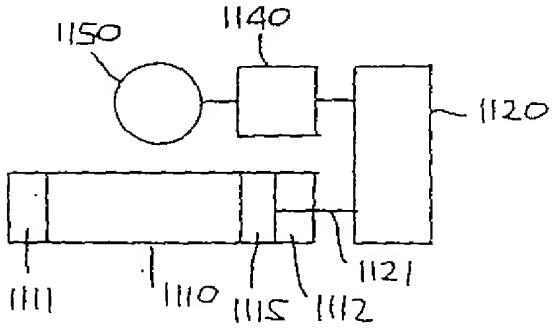


Fig. 25D

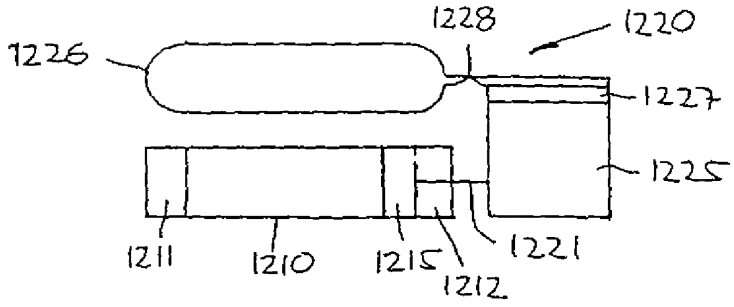


Fig. 25D

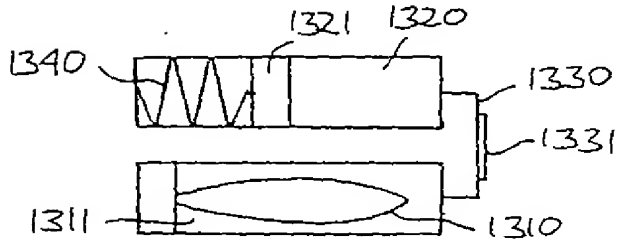


Fig.27

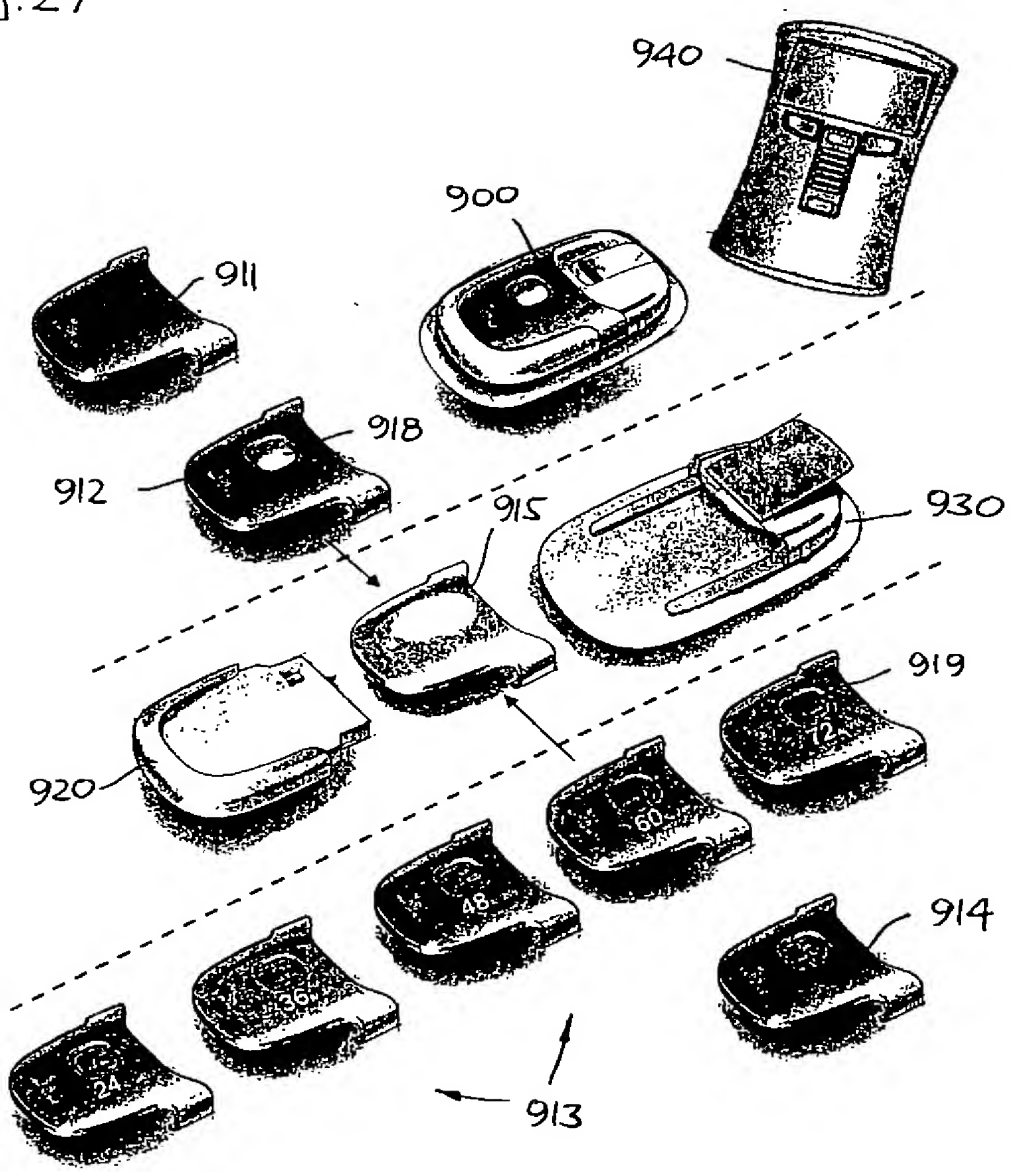


Fig. 28A

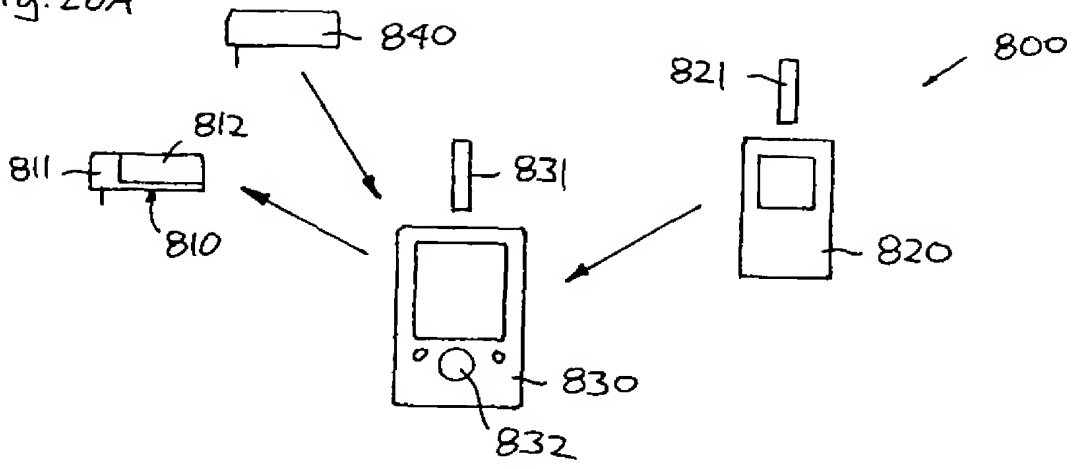


Fig. 28B

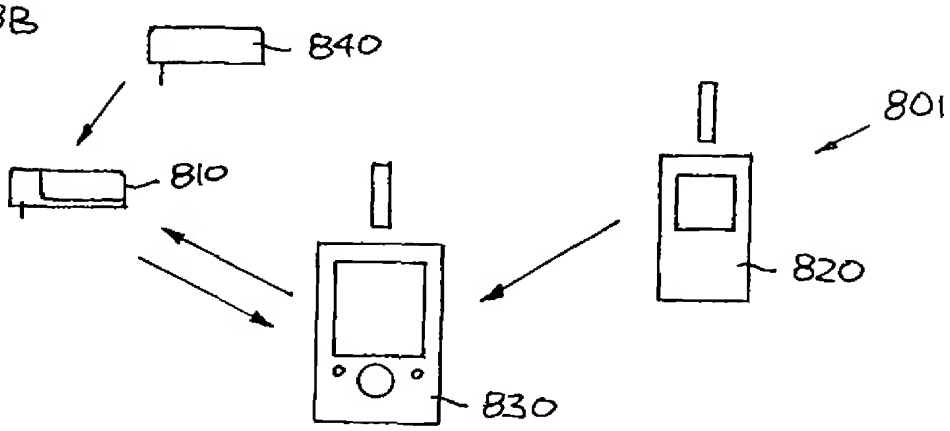


Fig. 28C

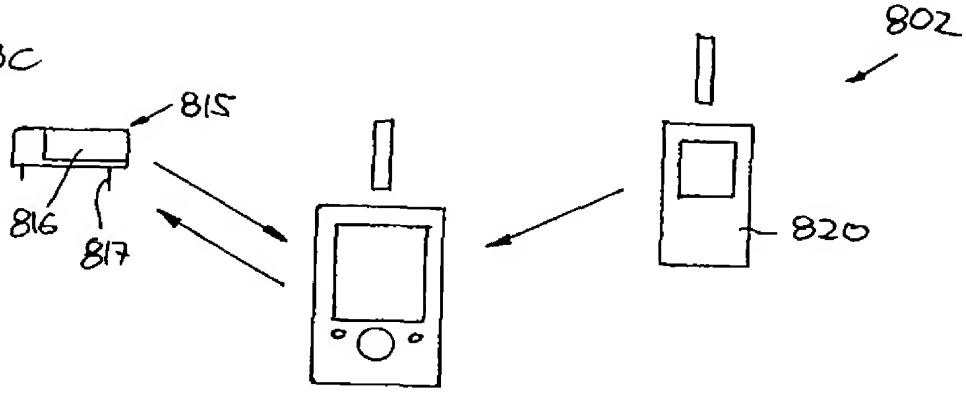


Fig. 29A

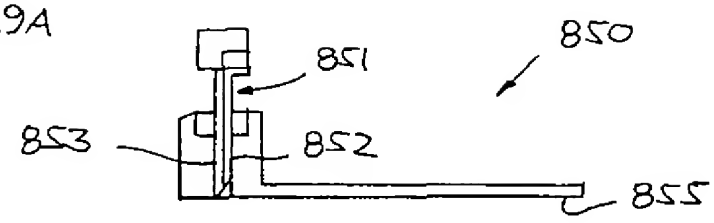


Fig. 29B

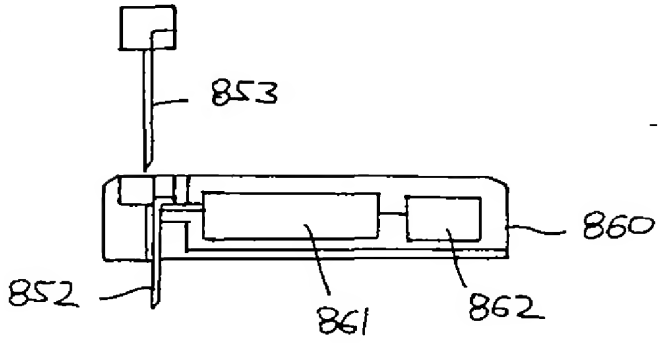


Fig. 30A

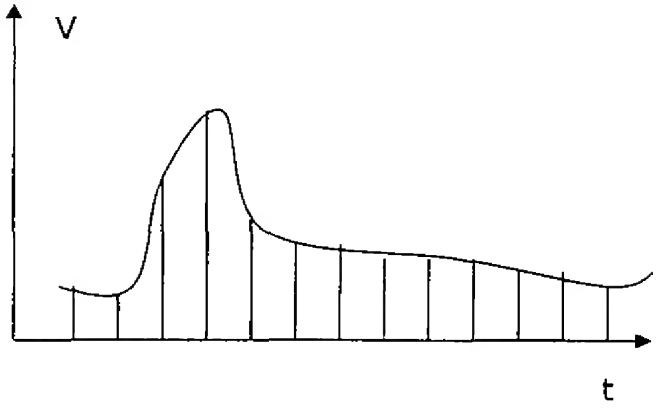
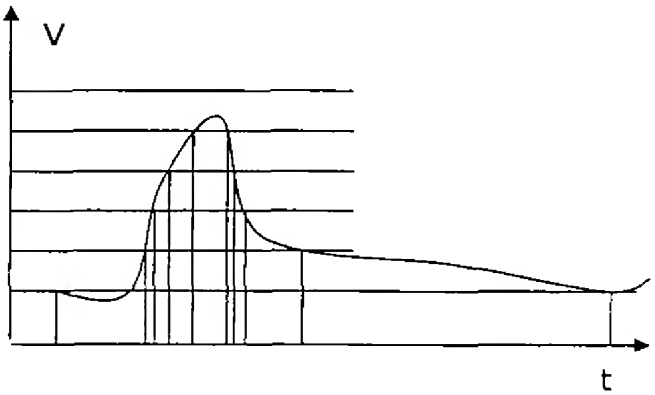


Fig. 30B



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/069464

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/142
ADD. G08C17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61N G08C H04Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 195 10 382 A1 (MUELLER & SEBASTIANI ELEK GMBH [DE]) 26 September 1996 (1996-09-26) column 2, lines 12-22 column 3, lines 36-68; figure 1	1-8, 12-15
Y	US 2005/182389 A1 (LAPORTE STEVE [US] ET AL) 18 August 2005 (2005-08-18) paragraphs [0058] - [0065], [0139] - [0141], [0154]; claims 1-4,19,38	1-15
Y	US 6 809 653 B1 (MANN ALFRED E ET AL) 26 October 2004 (2004-10-26) paragraphs [0053] - [0058]; figure 2	1-15

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 March 2007	10/04/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Krassow, Heiko

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/069464

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 289 361 A (MEDISTRON LTD; PRODUCT INNOVATION HOLDINGS LIMITED) 2 November 1988 (1988-11-02) column 6, lines 32-55	1-15
Y	US 2004/210267 A1 (LEBEL RONALD J ET AL) 21 October 2004 (2004-10-21) paragraphs [0106], [0222] - [0225]	1-15
Y	US 2004/093126 A1 (CAMPAGNOLO VALENTINO [IT] ET AL) 13 May 2004 (2004-05-13) paragraphs [0014] - [0018], [0025] - [0029], [0073] - [0076], [0102] - [0105]	1-15
Y	GB 2 342 205 A (PITTWAY CORP [US]) 5 April 2000 (2000-04-05) page 5, line 26 - page 7, line 2 page 7, line 24 - page 8, line 9 page 9, lines 18-22	1-15
Y	GB 2 286 055 A (BRITISH AUTOGARD [GB]) 2 August 1995 (1995-08-02) page 3, paragraphs 3,4 page 5, paragraph 6 - page 6, paragraph 1 page 13, paragraph 2	1-15
P,X	WO 2006/075016 A (NOVO NORDISK AS [DK]; BENGTSSON HENRIK [DK]; KRISTENSEN LEIF ENGMANN [) 20 July 2006 (2006-07-20) paragraphs [0021] - [0023], [0071] - [0075]; figures 1a-2b	1-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2006/069464

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16
because they relate to subject matter not required to be searched by this Authority, namely:

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery
The method defined in claim 16 implies surgically providing a needle sensor for continuously measuring a parameter in the body fluid of a patient.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2006/069464

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19510382 A1	26-09-1996	NONE	
US 2005182389 A1	18-08-2005	NONE	
US 6809653 B1	26-10-2004	AU 6255699 A	26-04-2000
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		JP 2002526137 T	20-08-2002
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		JP 2000113343 A	21-04-2000
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WO 2006075016 A	20-07-2006	NONE	